

EXHIBIT 92

IN RE: NATIONAL MDL No. 2804
5 PRESCRIPTION OPIATE
LITIGATION Case No.
6 1:17-MD-2804

THIS DOCUMENT RELATES TO Hon. Dan A. Polster
8 ALL CASES

10
11 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
12 CONFIDENTIALITY REVIEW
13 VIDEOTAPED DEPOSITION OF EILEEN SPAULDING

18 Held At:

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21 Boston, Massachusetts

23 REPORTED BY:

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	Page 2	Page 4
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	Page 3	Page 5
1 APPEARANCES (Continued):		1 INDEX
2 FOR McKESSON CORPORATION:		2 EXAMINATION
3 ALEJANDRO BARRIENTOS, ESQ. (Remotely)		3 EILEEN SPAULDING
4 COVINGTON & BURLING LLP		4 BY MR. GOTTO 10
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10		10 NO. DESCRIPTION PAGE
11 FOR WALMART:		11 Mallinckrodt- 11/11/09 e-mail, Bates
12 CHRISTOPHER MARKHAM, ESQ.		Spaulding-1 MNK-T1_0000278740..... 111
13 JONES DAY		12 Mallinckrodt- Document titled FY '10
14 100 High Street		Spaulding-2 Assessment, Bates
15 Boston, Massachusetts 02110		MNK-T1_0000490704 through
16 617-960-3939		720..... 115
17 cmarkham@jonesday.com		15 Mallinckrodt- E-mail chain, Bates
18		Spaulding-3 MNK-T1_0007026254 and 255.... 121
19 FOR PERNIX:		16 Mallinckrodt- E-mail chain, Bates
20 BRUCE CLARK, ESQ. (Remotely)		Spaulding-4 MNK-T1_0007730928 through
21 CLARK MICHIE LLP		930..... 133
22 220 Alexander Street		18 Mallinckrodt- E-mail chain, Bates
23 Princeton, New Jersey 08540		Spaulding-5 MNK-T1_0000274080 and 4081... 136
24 bruce.clark@clarkmichie.com		20 Mallinckrodt- 1/31/11 e-mail with
		Spaulding-6 attached PowerPoint, Bates
		MNK-T1_0005187729..... 140
		22 Mallinckrodt- Document titled Oxycodone
		Spaulding-7 Extended Release Risk Map
		Action Plan, Bates
		MNK-T1_0000448773 through
		780..... 144

		Page 6		Page 8	
1	Mallinckrodt- Spaulding-8	E-mail chain, Bates MNK-T1_0006443249..... 150	1	Mallinckrodt- Spaulding-32	E-mail chain, Bates MNK-T1_0000282686 and 687.... 239
2	Mallinckrodt- Spaulding-9	E-mail chain, Bates MNK-T1_0000492214 and 215.... 153	3	Mallinckrodt- Spaulding-33	E-mail chain, Bates MNK-T1_0000290887..... 242
4	Mallinckrodt- Spaulding-10	E-mail chain, Bates MNK-T1_0001792949 through 951..... 159	4	Mallinckrodt- Spaulding-34	E-mail chain, Bates MNK-T1_0003044340..... 242
6	Mallinckrodt- Spaulding-11	12/27/07 letter from DEA, Bates MNK-T1-0000270069 and 70..... 166	6	Mallinckrodt- Spaulding-35	E-mail chain, Bates MNK-T1_0000283719 through 721..... 246
8	Mallinckrodt- Spaulding-12	Document titled Suspicious Order Monitoring Team Charter, Bates MNK-T1_0000496062..... 172	8	Mallinckrodt- Spaulding-36	E-mail chain, Bates MNK-T1_0006055924 through 926..... 248
10	Mallinckrodt- Spaulding-13	E-mail chain with attachment, Bates MNK-T1_0007026341 and 342.... 174	10	Mallinckrodt- Spaulding-37	E-mail chain, Bates MNK-T1_0006056192..... 249
12	Mallinckrodt- Spaulding-14	E-mail chain, Bates MNK-T1_0004282621..... 178	11	Mallinckrodt- Spaulding-38	E-mail chain, Bates MNK-T1_0005641401 through 403..... 249
14	Mallinckrodt- Spaulding-15	E-mail chain, Bates MNK-T1_0000274399 and 400.... 180	13	Mallinckrodt- Spaulding-39	Clawed back - E-mail chain, Bates MNK-T1_0007729523..... 250
16	Mallinckrodt- Spaulding-16	E-mail with attachment, Bates MNK-T1_0002940798..... 184	15	Mallinckrodt- Spaulding-40	7/17/08 e-mail with attachment, Bates MNK-T1_0006442504 and 505.... 253
17	Mallinckrodt- Spaulding-17	E-mail chain, Bates MNK-T1_0005663239 through 242..... 188	17	Mallinckrodt- Spaulding-41	Administrative Memorandum of Agreement..... 256
19	Mallinckrodt- Spaulding-18	E-mail chain, Bates MNK-T1_0000280632 and 633.... 194	18	Mallinckrodt- Spaulding-42	Spreadsheet titled Oxy Percent of Sales by Dist by State, Bates MNK-T1_0008434332..... 284
21	Mallinckrodt- Spaulding-19	Document titled Suspicious Order Monitoring Program, Bates MNK-T1_0000477900 through 912..... 195	21	Mallinckrodt- Spaulding-43	E-mail chain with attachment, Bates MNK-T1_0007898862 through 864..... 287
23			23		
24			24		
		Page 7		Page 9	
1	Mallinckrodt- Spaulding-20	Document titled Notes from Meeting at DEA Albany Office, 11/01/10, Bates MNK-T1_0002357150 and 151.... 198	1	Mallinckrodt- Spaulding-44	6/29/12 e-mail with attachment, Bates MNK-T1_0007053962 through 966..... 298
4	Mallinckrodt- Spaulding-21	11/30/10 e-mail, Bates MNK-T1_0000270021..... 202	4	Mallinckrodt- Spaulding-45	CSC Steering Committee Meeting Notes, 12/12/12, Bates MNK-T1_000696775 through 777..... 304
5	Mallinckrodt- Spaulding-22	E-mail chain, Bates MNK-T1_0001519526 and 527.... 204	7	Mallinckrodt- Spaulding-46	Document titled HZQS - Controlled Substances Compliance Responsibilities Associated with Anti-Diversion, Bates MNK-TNSTA05335585 through 589..... 317
7	Mallinckrodt- Spaulding-23	10/18/11 e-mail with attachments, Bates MNK-T1_0000289371, and MAL-MI000030498 through 502.. 206	10	Mallinckrodt- Spaulding-47	Document titled HZQS - Identification, Investigation, and Reports of Controlled Substances Suspicious Orders, Bates MNK-TNSTA05335590 through 593..... 318
9	Mallinckrodt- Spaulding-24	3/15/11 e-mail with attachment, Bates MNK-T1_0000282467 through 474..... 209	14	Mallinckrodt- Spaulding-48	Document titled HZQS - Controlled Substances Compliance Responsibilities Associated with Suspicious Order Monitoring, Bates MNK-TNSTA05335581 through 584..... 319
11	Mallinckrodt- Spaulding-25	4/28/11 e-mail with attachment, Bates MNK-T1_0000283244 through 248..... 211	18	Mallinckrodt- Spaulding-49	E-mail chain with attachment, Bates MNK-T1_0007898351 through 354..... 320
13	Mallinckrodt- Spaulding-26	11/1/10 letter, Bates MNK-T1_0000288483 and 484.... 215	21		
15	Mallinckrodt- Spaulding-27	E-mail chain, Bates MNK-T1_0000422189 through 192..... 221	22		
17	Mallinckrodt- Spaulding-28	E-mail chain, Bates MNK-T1_0000485790 and 791.... 223	23		
19	Mallinckrodt- Spaulding-29	E-mail chain with attachment, Bates MNK-T1_0000561060 through 1062..... 227	24		
21	Mallinckrodt- Spaulding-30	E-mail chain, Bates MNK-T1_0000371673 and 674.... 229			
23	Mallinckrodt- Spaulding-31	E-mail chain, Bates MNK-T1_0005424123 through			

Page 10	Page 12
<p>1 P R O C E E D I N G S</p> <p>2</p> <p>3 THE VIDEOGRAPHER: We are now on the</p> <p>4 record. My name is Robert Martignetti, I'm a</p> <p>5 videographer for Golkow Litigation Services.</p> <p>6 Today's date is February 5, 2019, and the time</p> <p>7 is 9:06 a.m.</p> <p>8 This video deposition is being held in</p> <p>9 Boston, Massachusetts, In Re: National Opiate</p> <p>10 Litigation.</p> <p>11 The deponent is Eileen Spaulding.</p> <p>12 Counsel will be noted on the</p> <p>13 stenographic record.</p> <p>14 The court reporter is Maureen Pollard,</p> <p>15 and will now swear in the witness.</p> <p>16</p> <p>17 EILEEN SPAULDING,</p> <p>18 having been duly identified and sworn, was</p> <p>19 examined and testified as follows:</p> <p>20 EXAMINATION</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. Good morning, Ms. Spaulding.</p> <p>23 A. Good morning.</p> <p>24 Q. My name is Gary Gotto. We met briefly</p>	<p>1 Q. I'm pretty sure we can all be heard.</p> <p>2 We will take breaks periodically</p> <p>3 today, but if you need a break at any point, as</p> <p>4 long as there's not a question pending, just let</p> <p>5 me know, and we'll accommodate that. Okay?</p> <p>6 A. Okay.</p> <p>7 Q. By whom are you employed?</p> <p>8 A. Mallinckrodt.</p> <p>9 Q. And what's your business address?</p> <p>10 A. 172 Railroad Avenue, Hobart, New York</p> <p>11 13788.</p> <p>12 Q. And when did you first become employed</p> <p>13 at Mallinckrodt?</p> <p>14 A. December of 1998.</p> <p>15 Q. Before we get into your Mallinckrodt</p> <p>16 employment, just a little bit of background.</p> <p>17 Describe for me briefly your post-high school</p> <p>18 education.</p> <p>19 A. So I have an associate's in computer</p> <p>20 information systems technology from BYU. And I</p> <p>21 went into the workforce for Elastic Stop Nut for</p> <p>22 approximately two years after graduation. I</p> <p>23 then worked for J.L. Hammett School Supplies as</p> <p>24 a customer service rep for ten years, PSE&G as a</p>
<p>1 Page 11</p> <p>1 just before we went on the record. We've never</p> <p>2 met before today, correct?</p> <p>3 A. Correct.</p> <p>4 Q. Have you ever given a deposition</p> <p>5 previously?</p> <p>6 A. No.</p> <p>7 Q. Okay. Well, we will -- just a few</p> <p>8 items by way of background. Please let me</p> <p>9 finish my questions if you can, and I'll</p> <p>10 certainly try to let you finish your answers</p> <p>11 before so we don't speak over each other.</p> <p>12 If any of my questions are unclear to</p> <p>13 you in any way, let me know and I'll do my best</p> <p>14 to clarify them.</p> <p>15 A. Okay.</p> <p>16 Q. If you answer a question without</p> <p>17 asking for a clarification, I'll assume you felt</p> <p>18 like you understood it. Okay?</p> <p>19 A. Yes.</p> <p>20 Q. And this is kind of a large table so</p> <p>21 I'll try to keep my voice up so we can all hear</p> <p>22 each other. But I'm not shouting, I'm just</p> <p>23 trying to --</p> <p>24 A. I understand.</p>	<p>1 customer service rep for approximately two</p> <p>2 years, and then I relocated to New York and</p> <p>3 started with Mallinckrodt.</p> <p>4 Q. Okay. What is PSE&G?</p> <p>5 A. Public Service Electric & Gas. It's</p> <p>6 the electric company for the State of New</p> <p>7 Jersey.</p> <p>8 Q. Okay. And do you hold any</p> <p>9 professional licenses or certifications?</p> <p>10 A. No.</p> <p>11 Q. Approximately when did you get your</p> <p>12 associate's degree?</p> <p>13 A. I graduated in 1990.</p> <p>14 Q. Okay. All right. And prior to</p> <p>15 Mallinckrodt did you have any employment history</p> <p>16 that was related in any way to the</p> <p>17 pharmaceuticals industry?</p> <p>18 A. No.</p> <p>19 Q. In your undergraduate work did you</p> <p>20 take any coursework that related to the</p> <p>21 pharmaceuticals industry?</p> <p>22 A. No.</p> <p>23 Q. Have you done any other formal --</p> <p>24 apart from on-the-job training or internal</p>

Page 14	Page 16
<p>1 training programs provided at Mallinckrodt, any 2 other educational programs that you've taken 3 that relate in any way to the pharmaceuticals 4 industry?</p> <p>5 A. Not sure I understand what you mean. 6 Like DEA training seminars?</p> <p>7 Q. That would be -- let me -- the 8 pharmaceuticals industry -- well, let's be as 9 broad as we can. That relate to pharmaceuticals 10 in any way, so that would include anything 11 related to DEA training or the Controlled 12 Substances Act, anything of that nature.</p> <p>13 A. Yes. So I've attended several DEA 14 pharmaceutical training seminars sponsored by 15 the DEA; pharmaceutical industry conferences 16 also sponsored by DEA; HDMA, which is now known 17 as HDA, two of their conferences; and 18 BuzzoPDMA, now IQVIA, I've attended multiple 19 industry conferences.</p> <p>20 Q. Okay. And have those all been during 21 the time you were employed by Mallinckrodt?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. We'll get into that in just a 24 bit.</p>	<p>1 A. Yes. 2 Q. And did any of those documents refresh 3 your recollection in any regard? 4 A. Yes. 5 Q. And in what regards can you recall 6 your recollection being refreshed? 7 A. Well, once I'd read the e-mail, then 8 it would remind me of what the topic or the 9 subject matter was. 10 Q. Okay. Was there any particular matter 11 you can recall reviewing a document and having 12 that document refresh your recollection as to a 13 specific subject matter or event? 14 MR. O'CONNOR: I'm going to object, 15 and instruct the witness not to answer to the 16 extent it would get into which particular 17 documents we were looking at which would be 18 protected by the attorney/client communication 19 privilege and work product doctrine. 20 BY MR. GOTTO: 21 Q. So again, and I think this is 22 consistent with your counsel's instruction, I'd 23 like you to tell me not the document itself but 24 just the subject matter, what the event or the</p>
<p>1 Tell me what you did -- and I don't 2 want you to disclose any communications with 3 your counsel, but what did you do to prepare for 4 today's deposition?</p> <p>5 A. I met with my counsel.</p> <p>6 Q. Okay. And how many times did you meet 7 with counsel?</p> <p>8 A. Three.</p> <p>9 Q. And approximately when did you meet 10 with counsel?</p> <p>11 A. Two in January, and one yesterday.</p> <p>12 Q. And were those personal meetings or 13 telephonic?</p> <p>14 A. Personal.</p> <p>15 Q. And who was present?</p> <p>16 A. Kate and Andrew.</p> <p>17 Q. No one else?</p> <p>18 A. No.</p> <p>19 Q. Approximately how long did each one of 20 the meetings last?</p> <p>21 A. Seven to eight hours.</p> <p>22 Q. And you can just answer this yes or 23 no. Did you review any documents during those 24 meetings?</p>	<p>1 subject matter as to which you can recall your 2 recollection being refreshed by reviewing a 3 document. 4 MR. O'CONNOR: You can answer at a 5 general level. 6 A. Whatever the subject was of the 7 particular document I would remember upon 8 reading it. 9 BY MR. GOTTO: 10 Q. Sure. Okay. 11 Fair to say, then, there's not a 12 specific thing that comes to your mind as you're 13 sitting here today of, for example, reviewing a 14 document and having the sensation of oh, gee, I 15 forgot all about that meeting but now that I 16 review this document I remember there was such a 17 meeting, or anything of that nature that would 18 be more specific than just a general, well, I 19 see a document and that at some level, you know, 20 causes me to better remember something that 21 happened some years back? 22 A. No. 23 Q. Okay. Have you reviewed any 24 transcripts of any deposition testimony given by</p>

Page 18	Page 20
<p>1 any of the witnesses in this matter?</p> <p>2 A. No.</p> <p>3 Q. Have you had -- well, have you spoken</p> <p>4 to anyone who has given a deposition in this</p> <p>5 matter with respect to their deposition?</p> <p>6 A. Only that they had been deposed.</p> <p>7 Nothing of the subject matter.</p> <p>8 Q. Okay. And who did you speak to in</p> <p>9 that regard?</p> <p>10 A. Karen Harper.</p> <p>11 Q. Anyone else?</p> <p>12 A. No.</p> <p>13 Q. Have you reviewed any of the papers</p> <p>14 that have been filed in court related to this</p> <p>15 litigation, including any of the complaints</p> <p>16 filed by any of the plaintiffs?</p> <p>17 A. No.</p> <p>18 Q. Are you aware that there's in excess</p> <p>19 of a thousand complaints that have been filed by</p> <p>20 various governmental entities, counties,</p> <p>21 municipalities, etcetera, relating to the opioid</p> <p>22 epidemic?</p> <p>23 A. Yes.</p> <p>24 Q. And again without divulging any</p>	<p>1 Okay. Do you have at home any paper</p> <p>2 files that in any way relate to your work at</p> <p>3 Mallinckrodt?</p> <p>4 A. No.</p> <p>5 Q. And have you at any time?</p> <p>6 A. No. I apologize, I step back. I have</p> <p>7 taken work home previously to complete and bring</p> <p>8 back to work the next day.</p> <p>9 Q. Okay. But in terms of maintaining a</p> <p>10 file in a file --</p> <p>11 A. No, absolutely --</p> <p>12 Q. -- cabinet at your home or anything</p> <p>13 like that, that's not something that you do?</p> <p>14 A. No, absolutely not.</p> <p>15 Q. Okay. Well, let's talk about your</p> <p>16 employment at Mallinckrodt. I'd like first to</p> <p>17 just get a general sense of the positions that</p> <p>18 you've held over the years. I realize you've</p> <p>19 been there a long time and you may be a little</p> <p>20 fuzzy on particular dates, and that's fine.</p> <p>21 This isn't a memory contest. And we'll look at</p> <p>22 some documents that may pin down some dates from</p> <p>23 time to time as we go through today.</p> <p>24 But just at a general level, if you</p>
<p style="text-align: center;">Page 19</p> <p>1 communications with counsel, how did you first</p> <p>2 become aware of that?</p> <p>3 A. It's only through counsel that I am</p> <p>4 aware of that.</p> <p>5 Q. Is it a subject -- the litigation, is</p> <p>6 that a subject that you've had any conversations</p> <p>7 with anyone else at Mallinckrodt, again apart</p> <p>8 from communications with counsel?</p> <p>9 A. No.</p> <p>10 Q. Have you taken any steps to preserve</p> <p>11 any documents that might in any way relate to</p> <p>12 the subject matter of the opioid litigation?</p> <p>13 A. So we have a document preservation</p> <p>14 notice that's been issued, so all documents have</p> <p>15 been preserved.</p> <p>16 Q. Okay. But -- and that would apply to</p> <p>17 documents that, for example, are on Mallinckrodt</p> <p>18 servers or on your work computer, that sort of</p> <p>19 thing?</p> <p>20 A. I can only speak to my work computer.</p> <p>21 Q. Okay. In terms of -- do you have a</p> <p>22 personal computer at home?</p> <p>23 A. Actually, no, I don't.</p> <p>24 Q. You don't.</p>	<p>1 can tell me the positions that you've held over</p> <p>2 the years at Mallinckrodt.</p> <p>3 A. Sure. I started in their packaging</p> <p>4 department as a packaging operator in 1998. I</p> <p>5 was in that department for approximately a year</p> <p>6 and a half, and I transitioned into the</p> <p>7 validations department. And I was with</p> <p>8 validations for approximately two years. And</p> <p>9 then in April of 2001, I transitioned into the</p> <p>10 compliance role.</p> <p>11 Q. Okay. So prior to April of '01, in</p> <p>12 the packaging and validations positions, just</p> <p>13 tell me generally what responsibilities you had</p> <p>14 in those positions.</p> <p>15 A. In packaging it was working on the</p> <p>16 line that puts the tablets and capsules into the</p> <p>17 bottles, running the machinery.</p> <p>18 And then in validations it was</p> <p>19 executing protocols and taking samples to</p> <p>20 validate products for FDA approval.</p> <p>21 Q. Okay. And did you receive any</p> <p>22 training with respect to either of those</p> <p>23 positions?</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 22</p> <p>1 Q. What was the nature of the training?</p> <p>2 A. So in packaging would have been</p> <p>3 on-the-job training, classroom training, SOP</p> <p>4 training.</p> <p>5 The same for validations.</p> <p>6 Validations, I had in the beginning a one-on-one</p> <p>7 trainer that would show me how to take samples</p> <p>8 and execute the protocols, how to write reports.</p> <p>9 Q. And what is SOP training?</p> <p>10 A. Reading SOPs, standard operating</p> <p>11 procedures. We have a computer system that</p> <p>12 assigns us SOPs based on our curriculum, and we</p> <p>13 read those, and in some cases take -- there's a</p> <p>14 quiz associated with those SOPs.</p> <p>15 Q. Okay. You said April of '01 you</p> <p>16 transitioned to a compliance role. What was the</p> <p>17 compliance role that you transitioned into?</p> <p>18 A. So in April of 2001, the reason I</p> <p>19 remember the date is because that's when our</p> <p>20 distribution center opened, and a newly created</p> <p>21 position of compliance investigator -- excuse</p> <p>22 me, compliance investigator was created in which</p> <p>23 I did the ARCOS reporting. I would investigate</p> <p>24 any losses in transit with the carriers, made</p>	<p style="text-align: right;">Page 24</p> <p>1 manufacturers on behalf of Mallinckrodt.</p> <p>2 Q. So prior to having the distributor</p> <p>3 license, Mallinckrodt had a license to</p> <p>4 manufacture controlled substances, correct?</p> <p>5 A. Yes.</p> <p>6 Q. And so it would then -- what would it</p> <p>7 then do with the controlled substances after it</p> <p>8 manufactured them?</p> <p>9 A. It would send them to St. Louis for</p> <p>10 distribution.</p> <p>11 Q. And did Mallinckrodt in St. Louis have</p> <p>12 a distribution license?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. So the distributor license that</p> <p>15 was obtained in '01 was for the Hobart facility?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. So when you took the position</p> <p>18 of compliance investigator, to whom did you</p> <p>19 report at that time?</p> <p>20 A. Liz McPhail.</p> <p>21 Q. And what was her position?</p> <p>22 A. Purchasing manager.</p> <p>23 Q. And for how long did that reporting</p> <p>24 relationship continue?</p>
<p style="text-align: right;">Page 23</p> <p>1 sure our reports were filed on time, handled</p> <p>2 destruction of the pharmaceutical waste, and any</p> <p>3 other tasks as assigned.</p> <p>4 Q. Okay. And you indicated this was a</p> <p>5 new position that was created in '01, is that</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. And it was related to the</p> <p>9 establishment of the distribution center?</p> <p>10 A. Yes, it was an additional license that</p> <p>11 was started at the Hobart site.</p> <p>12 Q. And what was the nature of the</p> <p>13 additional license?</p> <p>14 A. A distribution center. So previous to</p> <p>15 that we had only had a manufacturing DEA license</p> <p>16 and an analytical license. The addition of the</p> <p>17 distribution center in Hobart created the need</p> <p>18 to have a DEA distributor license and a DEA</p> <p>19 exporter license.</p> <p>20 Q. And so the DEA distributor license,</p> <p>21 what did that permit Mallinckrodt to do that it</p> <p>22 hadn't done previously?</p> <p>23 A. To distribute either Mallinckrodt-made</p> <p>24 products or products that were made by other</p>	<p style="text-align: right;">Page 25</p> <p>1 A. I don't recall exactly.</p> <p>2 Q. Was it some number of years?</p> <p>3 A. A few years.</p> <p>4 Q. Okay. And to whom did you report</p> <p>5 after you no longer reported to Ms. McPhail?</p> <p>6 A. To the materials manager.</p> <p>7 Q. And who was that?</p> <p>8 A. Tim Bach, and then later Aaron</p> <p>9 Nikolaus.</p> <p>10 Q. And for how long did those reporting</p> <p>11 relationships continue?</p> <p>12 A. Again, a few years.</p> <p>13 Q. And after that to whom did you report?</p> <p>14 A. Karen Harper.</p> <p>15 Q. Do you recall approximately when you</p> <p>16 began reporting to Ms. Harper?</p> <p>17 A. 2008 sometime.</p> <p>18 Q. And do you recall what her position</p> <p>19 was at that time?</p> <p>20 A. Senior manager of controlled</p> <p>21 substances compliance.</p> <p>22 Q. And for how long did your reporting</p> <p>23 relationship with Ms. Harper continue?</p> <p>24 A. I'm still reporting to Karen Harper.</p>

<p style="text-align: right;">Page 26</p> <p>1 Q. Okay. The position compliance 2 investigator which you indicated was a new 3 position when you took it in '01, did you 4 receive a written job description or a list of 5 responsibilities?</p> <p>6 A. I don't remember.</p> <p>7 Q. How did you come to have that 8 position? Did you apply for it?</p> <p>9 A. Yes. There was a posting internally 10 which I applied and was interviewed and awarded 11 the position.</p> <p>12 Q. Do you recall by whom you were 13 interviewed?</p> <p>14 A. Liz McPhail was one of them. I don't 15 remember who the others were.</p> <p>16 Q. And did you have an understanding at 17 the time as to what in your background qualified 18 you for that position?</p> <p>19 A. I guess just being an operator and 20 familiar with our processes and our products.</p> <p>21 Q. And you listed a few items that you 22 had responsibility for, for example, ARCOS 23 reporting. What was ARCOS reporting?</p> <p>24 A. ARCOS reporting is -- at that time we</p>	<p style="text-align: right;">Page 28</p> <p>1 tell me at the beginning how you did it, and 2 then how that process changed over the years.</p> <p>3 A. So at the beginning it was a -- 4 basically a -- we call it DDS, dangerous drug 5 system, would compile all of the data for the 6 receipts, and the shipments, and download it 7 into ARCOS format, which is -- I don't know, 8 it's a specific format, and then we would 9 download it onto disk and mail that disk to DEA 10 quarterly. Over time we started reporting 11 monthly at the request of DEA. And then in time 12 DEA had enhanced their systems to be able to 13 report online.</p> <p>14 So now we have two computer systems 15 that we merged together, our manufacturing and 16 our distribution center inventory systems, we 17 merged those together into a file that converts 18 to ARCOS format, and we upload it via a portal 19 on a monthly basis.</p> <p>20 Q. Okay. When did it -- did the reports 21 convert from quarterly to monthly, if you 22 remember?</p> <p>23 A. I don't remember exactly when.</p> <p>24 Q. Is there anyone else involved in the</p>
<p style="text-align: right;">Page 27</p> <p>1 were reporting quarterly all of our 2 distributions to our next downstream direct 3 customer.</p> <p>4 Q. And those reports went to whom?</p> <p>5 A. DEA.</p> <p>6 Q. Okay. And so was it your -- you had 7 responsibility for completing those reports, is 8 that right?</p> <p>9 A. For the distributor license.</p> <p>10 Q. And do you continue to have that 11 responsibility today?</p> <p>12 A. Yes.</p> <p>13 Q. Tell me what the -- just in general 14 what the ARCOS report reports to the DEA?</p> <p>15 A. So ARCOS is Automation Reports 16 Consolidated Ordering System, and it is all of 17 our receipts, so any product that we bring in we 18 record and any product we ship out we record, 19 and so it's acquisitions and dispositions.</p> <p>20 Q. And how do you go about gathering the 21 data that you include in that report?</p> <p>22 A. For what time period? Because it's 23 changed.</p> <p>24 Q. Okay. Fair enough. Maybe you can</p>	<p style="text-align: right;">Page 29</p> <p>1 process of compiling the data and transmitting 2 the ARCOS reports?</p> <p>3 A. For which DEA license?</p> <p>4 Q. Well, are you involved in the ARCOS 5 reporting for other than the Hobart distribution 6 license?</p> <p>7 A. Now I am. Back at the beginning of my 8 role I was not. Now, as manager, there's 9 another person that works under me, and she does 10 the manufacturing DEA ARCOS, and I do the 11 distributor ARCOS.</p> <p>12 Q. Okay.</p> <p>13 A. And we're backup for each other.</p> <p>14 Q. Okay. And when did that come to be 15 that you had someone working under you that you 16 just described?</p> <p>17 A. In April of 2017.</p> <p>18 Q. So prior to the time that you had this 19 person working under you on the manufacturing 20 license, was there anyone else involved in 21 compiling or transmitting the ARCOS reports that 22 you had responsibility for?</p> <p>23 A. No.</p> <p>24 Q. Was there any process in place to</p>

<p style="text-align: right;">Page 30</p> <p>1 review the ARCOS reports that you prepared for 2 accuracy or completeness?</p> <p>3 MR. O'CONNOR: Object to form.</p> <p>4 A. I'm not sure I understand. It's a 5 computer download.</p> <p>6 BY MR. GOTTO:</p> <p>7 Q. Okay. So let's go back to when it was 8 a physical report that you were preparing and 9 sending to the DEA. There was an actual paper 10 report at some point, correct?</p> <p>11 A. No, it was a file that we just put 12 onto a disk. But ARCOS requires it in a 13 specific format, and it's not human readable.</p> <p>14 It's a number of fields all pressed together.</p> <p>15 Q. Okay. So you would input the data 16 into that format, is that how it would be 17 prepared?</p> <p>18 A. It would -- we have a computer program 19 that downloads it into that format.</p> <p>20 Q. And so your personal involvement in 21 the preparation of the reports, what does it 22 consist of?</p> <p>23 A. Executing those -- a series of steps 24 that allows the computer to pull down the sales</p>	<p style="text-align: right;">Page 32</p> <p>1 A. Both, you know, that the reports were 2 filed on time.</p> <p>3 Q. Okay. And other than timeliness, any 4 other aspect of the reporting that was subject 5 of any goals or reviews?</p> <p>6 A. Not that I can recall.</p> <p>7 Q. Do you have an understanding of the 8 purpose of the -- from the DEA's standpoint, do 9 you have an understanding of the purpose for the 10 ARCOS reports?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. At a very high level.</p> <p>13 BY MR. GOTTO:</p> <p>14 Q. And what's that understanding?</p> <p>15 A. Is that it reports all of the 16 acquisitions and distributions. My ARCOS report 17 tells DEA everything we've acquired and 18 everything we've distributed. And then if 19 there's error reports, DEA will send us -- after 20 we file the report, DEA sends us an error 21 report, and if there's errors in the ARCOS data, 22 then we fix those errors on the next quarterly 23 report, or now monthly report.</p> <p>24 Q. And does that happen regularly, that</p>
<p style="text-align: right;">Page 31</p> <p>1 data and convert it to ARCOS format, and then if 2 there's any manual transactions or errors or 3 returns, I would enter those into the computer 4 system which would download into that ARCOS 5 format.</p> <p>6 Q. Okay. So, and is that a description 7 that's still current?</p> <p>8 A. Yes.</p> <p>9 Q. Okay.</p> <p>10 A. And it's the same for both DEA 11 licenses.</p> <p>12 Q. Okay. So is there any process in 13 place at Mallinckrodt, or has there been at any 14 point, to review any of the steps that you take 15 that you just described for accuracy, errors, 16 completeness, etcetera?</p> <p>17 MR. O'CONNOR: Object to form.</p> <p>18 A. Not that I'm aware of.</p> <p>19 BY MR. GOTTO:</p> <p>20 Q. Okay. Is the ARCOS reporting function 21 something that is a subject of any annual goals 22 that you set or reviews that you receive?</p> <p>23 A. It was earlier in my career.</p> <p>24 Q. Okay. Goals or reviews or both?</p>	<p style="text-align: right;">Page 33</p> <p>1 there are errors?</p> <p>2 A. Not regularly, but on occasion.</p> <p>3 Q. And what's the nature of the errors 4 typically?</p> <p>5 A. If there's a keypunch of a wrong digit 6 and a wrong character that the system has 7 downloaded, or if a DEA number has been -- was 8 missed.</p> <p>9 Q. Okay. And the nature of the 10 information that you submit in the ARCOS report, 11 you indicated it's -- what you acquired and what 12 you distributed, at what level of detail is that 13 information? Is it by, for example, API, or how 14 is it categorized?</p> <p>15 MR. O'CONNOR: Objection to form.</p> <p>16 A. For which license?</p> <p>17 BY MR. GOTTO:</p> <p>18 Q. The distributor license.</p> <p>19 A. So it's by finished goods, SKU, so the 20 individual number of bottles, packaged unit, and 21 so the number of bottles received and number of 22 bottles shipped, if there was any returns from a 23 customer for any reason, or if there's been any 24 waste, scrap.</p>

Page 34	Page 36
<p>1 Q. Okay. And the bottles received in the 2 case of the Hobart facility, from whom would 3 they be received?</p> <p>4 A. They could be received from the Hobart 5 manufacturing facility, or from an external 6 manufacturer.</p> <p>7 Q. Okay. And so that manufacturer, 8 whether it's Mallinckrodt Hobart or another 9 manufacturer, they would be reporting on a 10 separate ARCOS report their receipt and then 11 sale of those manufactured goods, correct?</p> <p>12 A. Yes. Correct.</p> <p>13 Q. And that's not a process you're 14 involved in in the Hobart facility, correct, or 15 at least until April, 2001 -- 2017, you were not 16 involved in that process?</p> <p>17 MR. O'CONNOR: Object to form.</p> <p>18 A. No, I misunderstand.</p> <p>19 BY MR. GOTTO:</p> <p>20 Q. The process I'm referring to is 21 whatever ARCOS report related to Hobart's 22 manufacturing activities, that report is not 23 something that at least until April of 2017 you 24 had any involvement in, is that correct?</p>	<p>1 there was a -- if there was an issue or problem 2 with the manufacturing license ARCOS reporting 3 at Hobart you would sometimes get involved in 4 that. Do you recall any particular issues or 5 problems that arose from time to time?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. Nothing particular. If there was -- 8 an error on the report came back and Carrie 9 couldn't figure out what it was, I would help 10 her.</p> <p>11 BY MR. GOTTO:</p> <p>12 Q. In any of the -- you indicated early 13 on that there have been a number of 14 DEA-sponsored seminars or other training 15 sessions that you've attended. Has ARCOS 16 reporting been a subject of any of those 17 sessions?</p> <p>18 A. Yes.</p> <p>19 Q. And what's been the substance of that, 20 that you can recall?</p> <p>21 A. It was DEA training on the transaction 22 codes and the format. That's where they 23 introduced us to the new ARCOS portal for us to 24 be able to upload and what direction they were</p>
Page 35	Page 37
<p>1 A. I was aware of it. I would help if 2 there was a problem. But I was not the primary 3 person responsible for reporting.</p> <p>4 Q. Okay. Do you know who was the primary 5 person responsible for reporting?</p> <p>6 A. Prior to 2005 was Sabrina Fountain, 7 After 2005 was Carrie Johnson.</p> <p>8 Q. Okay. And currently the person who 9 does that reporting reports to you, is that 10 correct?</p> <p>11 A. Yes.</p> <p>12 Q. And who is that?</p> <p>13 A. Carrie Johnson.</p> <p>14 Q. So since April of 2017, are you 15 involved in actually working on the preparation 16 of the manufacturing license ARCOS report for 17 the Hobart facility?</p> <p>18 A. No.</p> <p>19 Q. Do you, in your capacity supervising 20 Ms. Johnson, do you review anything -- any of 21 the work that she does relative to that ARCOS 22 reporting?</p> <p>23 A. No.</p> <p>24 Q. You indicated that prior to 2017, if</p>	<p>1 moving in and, you know, what transaction codes 2 to use for what specific business activity.</p> <p>3 Q. Okay. One of the other subject 4 matters you indicated you had responsibility for 5 is losses in transit. What did you mean by that 6 phrase?</p> <p>7 A. So if the carrier -- if there was 8 damage or a loss while the product was in 9 transportation to the customer.</p> <p>10 Q. Okay. And is that something that's 11 the subject of a regular report, or is it 12 something that's just reported on as it occurs?</p> <p>13 A. Reported on as it occurs.</p> <p>14 Q. And how do you -- how would you become 15 aware of the circumstances that would then give 16 rise to such a report?</p> <p>17 A. We're either notified by the carrier 18 that they have a box that was damaged in 19 transit, or a customer may contact our customer 20 service department and say they received a box 21 that was damaged in transit.</p> <p>22 Q. Okay. And so once you receive word of 23 such an event, what do you do to act on that?</p> <p>24 A. If there's just damage only, then we</p>
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<p style="text-align: right;">Page 38</p> <p>1 would notify the carrier, give them the tracking 2 information, make them aware of the damage. 3 Corporate tracks them on a scorecard. I don't 4 know the details to that.</p> <p>5 And if there was contents missing, 6 then we would work with the carrier to find out 7 what happened to those contents and if they can 8 be recovered.</p> <p>9 Q. And is that something you personally 10 are involved in, working with the carrier when 11 there's missing contents?</p> <p>12 A. Yes.</p> <p>13 Q. And so how do you go about determining 14 whether those contents can be recovered?</p> <p>15 A. We will contact our security contacts 16 with the carrier, initiate an investigation, 17 they will start looking for the product in their 18 facilities and everywhere that package 19 transitioned. And it's typically the box has 20 busted open while handling on their automated 21 machinery and a case has become separated, in 22 which it goes to overgoods, and then overgoods 23 notifies me that they have Mallinckrodt product. 24 We bring it back to the distribution center and</p>	<p style="text-align: right;">Page 40</p> <p>1 the DEA?</p> <p>2 A. It's their loss/theft report. It 3 gives the details around the shipment and the 4 product and quantity that is unaccountable.</p> <p>5 Q. And is there such a report prepared 6 any time any amount of controlled substances is 7 lost in transit and not otherwise accounted for?</p> <p>8 A. I don't understand the question.</p> <p>9 Q. Well, so the 106 report, let me ask it 10 a different way, is that prepared on an 11 event-by-event basis that there was a particular 12 loss in transit that where a product cannot be 13 accounted for ultimately and, therefore, that 14 gives rise to a particular 106 report that goes 15 to the DEA?</p> <p>16 A. Yes.</p> <p>17 Q. And would that be -- is there any 18 minimum amount of missing product that if you 19 fall below the minimum you don't have to do the 20 106 report, anything like that?</p> <p>21 A. Mallinckrodt's policy is to report any 22 controlled substances not accounted for.</p> <p>23 Q. Okay. Even if it was one bottle?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 39</p> <p>1 send it for destruction.</p> <p>2 Q. And overgoods is what?</p> <p>3 A. Overgoods is the department in which 4 our specific carrier -- any loose box that's 5 found anywhere within their system and they 6 can't determine where it was coming from or 7 where it was going to because it's not in its 8 original shipping container with the labels goes 9 to overgoods, and then they inventory it, and 10 we'll have dedicated trace agents to be able to 11 try to locate who was either the shipper or the 12 recipient of that product.</p> <p>13 Q. Okay. So if the -- do losses in 14 transit ever result in a report that goes to the 15 DEA?</p> <p>16 A. Yes.</p> <p>17 Q. Under what circumstances?</p> <p>18 A. If the material is not located in 19 overgoods we will file a DEA 106 report, notify 20 them immediately.</p> <p>21 Q. Okay. And is that something that 22 you're responsible for preparing?</p> <p>23 A. Yes.</p> <p>24 Q. And what does the 106 report report to</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. Or one pill?</p> <p>2 A. Yes.</p> <p>3 Q. Can you give me a sense for the 4 frequency, and if this changed over time how it 5 changed over time, the frequency of filing 106 6 reports with the DEA that you worked on?</p> <p>7 A. There's not a frequency. It's if you 8 have a loss that can't be accounted for, you 9 report it.</p> <p>10 Q. Sure. I understand.</p> <p>11 In a typical, say, month period, do 12 you have an estimate of how many 106 reports on 13 average you would have filed?</p> <p>14 A. In what time frame?</p> <p>15 Q. Well, again, if it changed over 16 time -- really the entire time that you've been 17 responsible, but if it's changed over time, you 18 know, how that's changed.</p> <p>19 MR. O'CONNOR: Objection to form.</p> <p>20 A. We had more frequent losses in transit 21 when we were using one particular carrier 22 service, so I don't remember exactly. I know 23 that there was more, which is the reason we 24 changed the carrier service and upgraded to an</p>

<p style="text-align: right;">Page 42</p> <p>1 express service in which our packages got more 2 prioritized handling and pre-alerts so that each 3 station knew when a Mallinckrodt package was 4 coming through so that they could watch it and 5 make sure it was under CCTV coverage, and our 6 106s dropped dramatically. Currently I file 7 maybe, rough estimates, I don't have my records 8 in front of me, four to five a year.</p> <p>9 BY MR. GOTTO:</p> <p>10 Q. So the carrier that you changed from, 11 who was the carrier that you had more loss 12 experience with?</p> <p>13 A. It was FedEx Ground service, which 14 back in that -- in the early time was formerly 15 known as RPS, Roadway Packaging Services. And 16 they weren't handling our product appropriately 17 and we were experiencing a lot of damages, so 18 our corporate transportation team transitioned 19 to FedEx Express services.</p> <p>20 Q. Okay. Do you recall when that -- 21 about when that transition occurred?</p> <p>22 A. I don't recall exactly.</p> <p>23 Q. Was it, say, before 2012?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 44</p> <p>1 106, and then you subsequently find out from 2 FedEx that they're able to locate the product, 3 do you then update the DEA on that, or -- 4 A. Yes. We file an amended DEA 106 and 5 send the DEA a cover letter stating that the 6 material has been recovered and brought back to 7 the distribution center and destroyed.</p> <p>8 Q. Okay. So your estimate, I realize 9 it's a rough estimate, of four to five 106 10 reports a year for the last several years, are 11 those 106 reports as to which ultimately the 12 product was never actually recovered? Is that 13 fair?</p> <p>14 A. I don't know without looking at the 15 records.</p> <p>16 Q. Okay. That estimate of roughly four 17 to five a year, would that go back to as far 18 back as whenever it was that you made the 19 transition away from FedEx Ground?</p> <p>20 A. I'd have to look at the records. I 21 know what currently, they're approximately four 22 to five years -- or four to five a year. I 23 don't recall specifically what they are prior, 24 for past years.</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. Before 2010?</p> <p>2 A. It was mid 2000s. Could have been '5, 3 '6, '7, '8.</p> <p>4 Q. So probably before 2010?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And were the problems primarily 7 damage, or were they losses that ultimately 8 couldn't be accounted for?</p> <p>9 MR. O'CONNOR: Object to form.</p> <p>10 A. They were predominantly damages.</p> <p>11 BY MR. GOTTO:</p> <p>12 Q. Okay. And so am I understanding 13 correctly if there's damage but the product is 14 all accounted for, that doesn't result in a 106 15 report, correct?</p> <p>16 A. It depends on whether it was recovered 17 quickly, because we have to report within 18 24 hours. So if we could report -- if we could 19 recover within FedEx within 24 hours and we knew 20 they had the product, it was in as overgoods, 21 then we would not file. If we couldn't locate 22 the product within 24 hours, we would file.</p> <p>23 Q. Okay. And what would happen if you 24 couldn't locate within 24 hours so you filed the</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. Okay. So, for example, let's say that 2 2010 to 2014 time frame, do you have any sense 3 of how -- of the average number of 106 reports 4 that were filed in that time frame?</p> <p>5 A. No, I don't.</p> <p>6 Q. Okay. During the period of when you 7 were using FedEx Ground, do you have a sense for 8 approximately how many, on average, how many 9 106s on average were filed annually?</p> <p>10 A. Not an exact number. It was 11 significantly higher than what we currently 12 have.</p> <p>13 Q. Was it twice as many?</p> <p>14 A. I don't remember exactly.</p> <p>15 Q. Okay. I'd like to understand, and I 16 realize since 2001 we're dealing with a long 17 time period here and some of this is going to 18 necessarily be, you know, a little fuzzy perhaps 19 as to specific dates and that sort of thing, but 20 I'd like to understand how your job 21 responsibilities changed over the years, if they 22 have changed. So if you can just -- let's start 23 with sort of a general description of how those 24 responsibilities have changed over the years.</p>

<p style="text-align: right;">Page 46</p> <p>1 A. So I have received promotions 2 throughout the years into different levels 3 within the compliance group. I started out with 4 just basic clerical, the ARCOS reporting, data 5 entry of waste transactions, discrepancy 6 reporting with the carriers. Then my 7 responsibilities increased in which I took on 8 facilitating and organizing the destruction of 9 the waste, not just doing the data entry. Took 10 on more responsibility in terms of just 11 workload, still doing the clerical but then 12 doing -- more involved with walk-throughs 13 through the facility, learning more about CFR 14 and the regulations, attended the training 15 seminars, learned about quota, and then I was a 16 compliance analyst for a length of time, and 17 then promoted into senior controlled substance 18 compliance coordinator, facilitated DEA audits, 19 was the DEA contact, was on the CSOS working 20 team when DEA was instituting CSOS to our 21 electronic 222 forms, and then was promoted into 22 the role of manager in April of 2017.</p> <p>23 Q. Great. Thank you. Let's go through 24 some of those items.</p>	<p>1 substance, and those get -- they're documented, 2 weighed, documented on our destruction reports. 3 We enter -- our team enters that into our 4 computer system, which then currently sends all 5 of the waste to a waste distributor for 6 destruction by incineration.</p> <p>7 Q. And you indicated your team still 8 does -- is still responsible for that. Who on 9 your team currently has that responsibility?</p> <p>10 A. Carrie Johnson has the data entry 11 portion.</p> <p>12 Q. Okay. Next item you indicated was 13 discrepancy reporting. What's that?</p> <p>14 A. So that's what we were talking about 15 earlier with the carriers -- excuse me, with the 16 carriers that if there's any discrepancies in 17 what we ship versus what the customer ordered, 18 or if the customer ordered a wrong product or we 19 shipped a wrong product in error, any difference 20 than what was intended to be ordered.</p> <p>21 Q. Okay. And so some of those 22 discrepancies are the result of damage in 23 transit, the sort of thing you discussed -- 24 described a little earlier today. It sounds</p>
<p style="text-align: right;">Page 47</p> <p>1 I think we've -- the ARCOS reporting 2 responsibility, I think you've already 3 described, is a continuing one that you still 4 have for the distribution license at Hobart, 5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. Apart from the testimony you've 8 already given us this morning, is there any 9 other aspect of ARCOS reporting that's been your 10 responsibility?</p> <p>11 A. Currently?</p> <p>12 Q. Or at any time.</p> <p>13 A. Well, currently the manufacturing is 14 done by a person who reports to me, so I oversee 15 that. But nothing else in regards to ARCOS.</p> <p>16 Q. Okay. And waste data entry, which 17 you'd indicated was an early on responsibility, 18 is that something you still have responsibility 19 for?</p> <p>20 A. My team, but not myself.</p> <p>21 Q. And what does that waste data entry 22 consist of?</p> <p>23 A. So we track every single tablet, 24 powder, capsule of waste that's a controlled</p>	<p>1 like sometimes there's a misfilling of an order, 2 though. What happens in those situations?</p> <p>3 MR. O'CONNOR: Objection to form.</p> <p>4 A. Because of our cycle count program in 5 the processes in the distribution center, we 6 have not had in the last ten years a shipping 7 error where we meant to ship sugar-free and we 8 shipped cherry or something, because of the bar 9 coding system.</p> <p>10 Prior to that there could have been an 11 instance where the wrong product was shipped, 12 and then the customer would say, hey, we've 13 received the wrong product, we'd make 14 arrangements to issue them a 222 form, we would 15 document what happened, that it was our mistake, 16 how we fix it, and then would make sure that the 17 customer had all of the documentation they 18 needed to document what happened, that they 19 received the wrong item, it was returned back to 20 Mallinckrodt, we received the incorrect item, we 21 sent it for destruction.</p> <p>22 BY MR. GOTTO:</p> <p>23 Q. Okay. And you also indicated 24 sometimes the customer may have ordered the</p>

<p style="text-align: right;">Page 50</p> <p>1 wrong item.</p> <p>2 A. Frequently we have situations where a 3 customer will enter the wrong item in their 4 order entry screen. They want buprenorphine 5 8.2-milligram and they ordered buprenorphine 6 2.5-milligram and they get it and it's the wrong 7 product and they have to send it back to us. 8 And that's frequent we have customer ordering 9 errors.</p> <p>10 Q. Okay. And in that situation, is there 11 any sort of report that gets generated when that 12 happens, or --</p> <p>13 A. The --</p> <p>14 Q. -- how is it handled?</p> <p>15 A. I apologize.</p> <p>16 The discrepancy report would document 17 what transpired, and then we would document 18 appropriately what actions we took to rectify.</p> <p>19 Q. Okay. And that discrepancy reporting, 20 is that something that you're personally 21 involved in?</p> <p>22 A. Yes.</p> <p>23 Q. Another item you mentioned was 24 destruction of waste. Is that the process you</p>	<p style="text-align: right;">Page 52</p> <p>1 were walk-throughs. What did you mean by that?</p> <p>2 A. So we go up on the manufacturing floor 3 and just walk through the facility daily to make 4 sure that materials are being stored in 5 compliance with the regulations, there's nothing 6 being left out, there's no residual powders 7 anywhere they shouldn't be, everything is 8 sealed. Just being there for questions for the 9 floor, if somebody has a question, how do they 10 handle something.</p> <p>11 Q. Okay. And so when you say we do that 12 daily, who is "we" in that setting?</p> <p>13 A. I do it daily. When I'm not there, a 14 member of my team will do it.</p> <p>15 Q. So describe for me, if you would, the 16 Hobart facility, just the physical setup 17 relative to your office. For example, since you 18 walk through it daily, about how large is the 19 facility?</p> <p>20 A. I'm not -- I don't know square footage 21 or any of that kind of thing. It's a big 22 facility, but I don't know the square footage.</p> <p>23 Q. Is it multi-story?</p> <p>24 A. Yes, there are multiple floors.</p>
<p style="text-align: right;">Page 51</p> <p>1 have described a few moments ago where you 2 shipped the waste to a reverse distributor for 3 destruction?</p> <p>4 A. Yes.</p> <p>5 Q. And is that -- shipment of that waste, 6 is that documented with the DEA somehow?</p> <p>7 A. It's -- if they're C1 and 2s, they are 8 documented by a 222 form; 3, 4s and 5s, a 9 transfer of controlled substance form, and it is 10 ARCos reported as well.</p> <p>11 Q. Okay. So the -- either the 222 form 12 or the transfer form that you mentioned, are 13 those things that you have responsibility for?</p> <p>14 A. Yes.</p> <p>15 Q. Is there a regular process for the 16 destruction of waste, or is it handled on an 17 as-needed basis?</p> <p>18 A. Monthly we schedule a pickup by the 19 reverse distributor to take care of all of the 20 waste generated from the previous month because 21 it has to be stored in cages and vaults, so if 22 we don't have it removed monthly, we tend to run 23 into space problems.</p> <p>24 Q. Okay. Another thing you mentioned</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. Okay. So the walk-through that you do 2 every day, how long does it take you?</p> <p>3 A. 45 minutes to an hour.</p> <p>4 Q. Okay. Are there particular things you 5 look for when you're doing the walk-through?</p> <p>6 A. Just to make sure everything is stored 7 appropriately and within compliance.</p> <p>8 Q. And one of the -- actually right after 9 the walk-throughs you indicated learning more 10 about the CFRs and regulations, and part of your 11 walk-through, I take it, is to satisfy yourself 12 that the facility is in compliance with 13 applicable regulations, correct?</p> <p>14 A. To ensure we're always in compliance, 15 yes.</p> <p>16 Q. And so describe for me the process 17 you've gone through over the years to learn 18 about and stay current on the applicable 19 regulations.</p> <p>20 A. So I've read CFR a number of times. I 21 refer to it often if there's questions. If we 22 were unsure of an interpretation of CFR, we may 23 have reached out for DEA to their field office 24 for interpretation or asked them while they were</p>

<p style="text-align: right;">Page 54</p> <p>1 on-site for an audit, so I've learned from DEA 2 what their expectations are, what they want. I 3 attended the DEA training seminars that are 4 sponsored by DEA in which they go over their 5 expectations or break down CFR into more detail. 6 We do practice exercises on quota at 7 those training seminars, they talk about imports 8 and exports, how to fill out the forms, and how 9 to do the calculations in the way that they want 10 them so that they can process them more 11 efficiently. 12 Q. Okay. Is that a -- do you still go to 13 the seminars that DEA sponsors? 14 A. When they have them. They haven't 15 been having them as more -- as frequently as 16 they did. They used to have them every other 17 year, and it's been a couple of years since 18 they've had them. 19 Q. Okay. So during the time since 2001 20 when you became involved in compliance, about 21 how many DEA-sponsored trainings have you been 22 to? 23 A. More than a dozen. 24 Q. And are these multi-day programs?</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. Which are those? 2 A. Suspicious order monitoring, state 3 licensing, exports. DEA has an initiative with 4 streamlining the Customs documentation through a 5 database with exports. 6 Q. So let me be sure -- I just want to be 7 sure I've covered all the various sort of formal 8 DEA-related training conferences and seminars 9 that you've gone to. 10 You indicated about a dozen or so of 11 the DEA-sponsored programs, although there 12 hasn't been one in the last at least couple of 13 years, correct? 14 A. Correct. 15 Q. And the Buzzeo, those are one a year? 16 A. Annual, yeah. 17 Q. Okay. Are there other training 18 programs of that type that you've attended? 19 A. NADDI, but not -- NADDI, they have DEA 20 speakers sometimes, but it's more about what's 21 going on in the industry. 22 Q. And do you attend the NADDI 23 conferences regularly? 24 A. I have occasionally.</p>
<p style="text-align: right;">Page 55</p> <p>1 A. Usually they're two days. 2 Q. And you also indicated you attended 3 the Buzzeo training, correct? 4 A. Yes. 5 Q. How often have you done that? 6 A. Just about every year. 7 Q. Up to the current? 8 A. Yes. 9 Q. What's the subject matter that's 10 typically covered at the Buzzeo conferences? 11 A. They usually have a DEA speaker that's 12 talking about NPRMs and what's on their agenda 13 and what they're working on. They'll have 14 subject matter experts on state licensing, and 15 different laws that individual states are 16 enacting in regards to controlled substances. 17 They'll have roundtable discussions on industry 18 topics. It's usually a two-and-a-half-day 19 conference. 20 Q. Okay. Are there particular, for 21 example the roundtable discussions, particular 22 ones that you make a point of participating in 23 at these conferences? 24 A. Yes.</p>	<p style="text-align: right;">Page 57</p> <p>1 Q. About how many times? 2 A. Half dozen roughly. 3 Q. How recently can you recall going to 4 one? 5 A. Last year. I went to a NADDI 6 conference last year. 7 Q. Are they annual? 8 A. They are. 9 Q. Okay. Apart from NADDI, Buzzeo, and 10 the DEA-sponsored, any other ones you can think 11 of? 12 A. Years ago I attended the 13 Pharmaceutical Security Coalition, PSC, many 14 years ago, and it was only once. It was more 15 geared towards physical security. 16 Q. In one of your answers a moment ago 17 you made reference to NPRM? 18 A. Notice of proposed rulemaking. 19 Q. Okay. Thank you. 20 Do you recall any particular proposed 21 rules that were covered in any of the 22 conferences you attended? 23 A. Recently there is one for paper. 24 They're trying to eliminate the carbon 222</p>

<p style="text-align: right;">Page 58</p> <p>1 forms, so there's been a Notice of Proposed 2 Rulemaking for one-page 222 forms. And there 3 was a recent one, but off the top of my head 4 it's escaping me.</p> <p>5 Q. Okay.</p> <p>6 A. Quota, there's a recent NPRM regarding 7 quota.</p> <p>8 Q. You've mentioned quota a couple of 9 times. What's been your responsibility over the 10 years with respect to quota?</p> <p>11 A. Initially I had very little to do with 12 quota. In more recent years I've been involved 13 with compiling and reviewing the quota letters 14 for increases throughout the year. The initial 15 quota requests are prepared by my team, and I 16 review.</p> <p>17 Q. When you say "quota," what do you -- 18 just so the record is clear what we're talking 19 about here, what do you mean by quota?</p> <p>20 A. Quota is the DEA allocation system 21 to -- for the manufacturing of controlled 22 substances.</p> <p>23 Q. And would your involvement be with 24 respect to the manufacturing activities at the</p>	<p style="text-align: right;">Page 60</p> <p>1 I would assist and review for a second set of 2 eyes, and then Karen Harper ultimately approved 3 the letter for submission. Carrie at that time 4 prior to 2017 reported directly to Karen Harper.</p> <p>5 Q. Okay. And so the actual submission, 6 has that always been Ms. Harper's 7 responsibility?</p> <p>8 A. To review -- I need clarification of 9 actual submission, entering into the database 10 or --</p> <p>11 Q. Yeah. Well, let me back up. 12 You said -- you made reference to your 13 involvement being a second set of eyes. Was 14 there any time when you had more involvement 15 than simply being a second set of eyes?</p> <p>16 A. Currently I do.</p> <p>17 Q. Okay. And so when did you take on 18 that additional responsibility?</p> <p>19 A. When Carrie Johnson started reporting 20 to me.</p> <p>21 Q. In 2017?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. So prior to 2017 when 24 Ms. Johnson started to report to you, in the</p>
<p style="text-align: right;">Page 59</p> <p>1 Hobart facility?</p> <p>2 A. Yes, quota only applies to the 3 manufacturing license. It doesn't apply to the 4 distributor license.</p> <p>5 Q. And is it specific to facility by 6 facility?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And so to the extent there's a 9 quota for Mallinckrodt St. Louis facility, 10 that's not something you have involvement with, 11 is that correct?</p> <p>12 A. Correct.</p> <p>13 Q. Okay. Do you know who has the 14 corresponding role, the role that corresponds to 15 your role at Hobart with respect to the 16 St. Louis quota for manufacturing?</p> <p>17 A. That would be my counterpart, Dave 18 Hunter.</p> <p>19 Q. Okay. And the quota that -- focusing 20 on the Hobart-related quota that you do have 21 responsibility for, when did you first have 22 responsibility for quota?</p> <p>23 A. So it was predominantly overseen by 24 Karen Harper, it was compiled by Carrie Johnson,</p>	<p style="text-align: right;">Page 61</p> <p>1 second set of eyes role that you mentioned, what 2 did your activities consist of with respect to 3 quota?</p> <p>4 A. Remote -- reviewing it for grammatical 5 content in terms of if I had heard through my 6 role maybe we had taken on a new contract or 7 been awarded business and Carrie hadn't included 8 that in a request, I would remind her about that 9 or let her know about that so it could be 10 inclusive in the request advising DEA of all the 11 information that we had available to us.</p> <p>12 Q. Okay. And you indicated that 13 initially you had very little responsibility 14 for -- with quota, and that changed over time. 15 Did you have more responsibility when you began 16 reporting to Ms. Harper?</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. I don't understand the question.</p> <p>19 BY MR. GOTTO:</p> <p>20 Q. I'm just trying to understand when you 21 started to have this additional responsibility, 22 the second eyes review of the quota 23 applications.</p> <p>24 A. So that would have been -- I got more</p>

<p style="text-align: right;">Page 62</p> <p>1 involved in roughly '14, '15, 2014, 2015. 2 Carrie and I both reported to Karen. Carrie had 3 her set of responsibilities. I had my set of 4 responsibilities. But in roughly '14 or '15, I 5 was cross-training more and taking on more 6 responsibilities to advance to manager, so in 7 that learning I needed to learn more about 8 quota, so then I started getting more involved 9 in quota.</p> <p>10 Q. Okay. So what did you do to learn 11 more about quota?</p> <p>12 A. More thorough on the letters, 13 understanding them, learned more about the 14 market and the dynamics that go on in the supply 15 chain, and the quota section training on the -- 16 from the DEA seminars.</p> <p>17 Q. And so the DEA seminars on quota 18 training, what are the topics they cover in that 19 context?</p> <p>20 A. Research versus manufacturing, where 21 does the quota belong, when do you start needing 22 quota. Karen mentored me because she had a lot 23 of experience with quota.</p> <p>24 Q. So when you say "research versus</p>	<p>1 then if that initial grant is not enough to 2 support, get you through the full calendar year, 3 you can ask for more quota throughout the year. 4 Q. Okay. And so that initial grant is 5 granted with respect to an upcoming calendar 6 year?</p> <p>7 A. Yes, it's applied for on April 12th of 8 the preceding year, so we take -- for example, 9 this April 1st coming up we will take our supply 10 plan for 2020 of what's needed in the market and 11 convert that into API, so how much API we need, 12 and then that will be applied for with DEA by 13 April 1st for 2020.</p> <p>14 Q. Okay. And then the DEA acts on that 15 application at some point prior to the upcoming 16 January 1, provides the quota allocation for the 17 upcoming calendar year, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And so the quota allocation -- when 20 you say API, I mean, that's active 21 pharmaceutical ingredient, correct?</p> <p>22 A. Yes.</p> <p>23 Q. And so is the quota for -- that the 24 DEA grants for the upcoming year, is that on an</p>
<p style="text-align: right;">Page 63</p> <p>1 manufacturing," what did you mean by that?</p> <p>2 A. So there's researcher license and 3 there's manufacturing licenses, and quota is not 4 required on a research license but it is 5 required on a manufacturing license, so what 6 project development work can be executed under a 7 research license not requiring quota, and what 8 project development work needs to be executed on 9 a manufacturing license that does require quota.</p> <p>10 Q. Okay. And is that also what you meant 11 when you said when you start needing quota, is 12 that this research versus manufacturing 13 distinction?</p> <p>14 A. No, when we start needing quota is 15 when the current quota is not sufficient for our 16 demand plan and we need to ask for more quota, 17 reviewing the market demand, the -- what's 18 needed, and how much we have will last us.</p> <p>19 Q. Describe for me generally how the 20 quota process works from your perspective. The 21 DEA provides a quota allocation for the Hobart 22 manufacturing facility from time to time, 23 correct?</p> <p>24 A. Yes. We have an initial grant, and</p>	<p style="text-align: right;">Page 65</p> <p>1 API by API basis?</p> <p>2 A. Yes.</p> <p>3 Q. And is it --</p> <p>4 A. By molecule.</p> <p>5 Q. By molecule.</p> <p>6 Okay. So it isn't with respect to a 7 particular dosage, for example, is that right?</p> <p>8 A. I don't understand what you mean.</p> <p>9 Q. So, for example, would you have a 10 certain allocation of oxycodone for the calendar 11 year as compared to an allocation of 12 20-milligram tablets, 30-milligram tablets, 13 etcetera?</p> <p>14 A. Yes, your application is submitted by 15 dosage form.</p> <p>16 Q. Okay. So for each API, the API is 17 then broken down to -- in different dosages?</p> <p>18 A. Yes.</p> <p>19 Q. And that's how, ultimately the DEA 20 when they grant the quota, that's how it's 21 granted?</p> <p>22 A. I don't know what formula DEA uses to 23 grant it. We fill our application, and we tell 24 DEA what we want and what we're going to make</p>

Page 66	Page 68
<p>1 with it. Very, very seldom do we get a 2 100 percent grant. 3 Q. Okay. But whatever grant you get, it 4 is expressed in terms of by API by dosage? 5 A. When we are given the grant we are 6 given just the total API, so we apply for it 7 specifying the dosage, but when the grant comes 8 there's no dosage specified, and if they haven't 9 given us 100 percent we don't know what they're 10 expecting us to make with it. 11 Q. Okay. So let's just use oxycodone for 12 an example, that's an API, correct, oxycodone? 13 A. Yes. 14 Q. Okay. And so when you submit the 15 application, you would have that broken down in 16 various dosages? 17 A. Yes. 18 Q. And a certain number of tablets in 19 each dosage, correct? 20 A. Yes. 21 Q. And you could add up how many 22 molecules are in all those tablets and then come 23 up with a gross amount of oxycodone API that's 24 covered by your application, correct?</p>	<p>1 the quota that was granted? 2 A. No. 3 MR. GOTTO: Okay. Why don't we take a 4 short break. We've been going for over an hour. 5 THE VIDEOGRAPHER: The time is 6 10:13 a.m., and we're off the record. 7 (Whereupon, a recess was taken.) 8 THE VIDEOGRAPHER: The time is 9 10:31 a.m., and we're on the record. 10 BY MR. GOTTO: 11 Q. Ms. Spaulding, before we broke we 12 were -- you were testifying about the quota 13 process and some aspects of it. And if I 14 understand correctly, from time to time there 15 can be applications for an update to the quota 16 during the calendar year, is that correct? 17 A. An increase, yes, we can request an 18 increase at any time. 19 Q. And is that a process that you're 20 involved in? 21 A. What time frame? 22 Q. Well, have you been involved in it at 23 any time frame since you've been at 24 Mallinckrodt?</p>
<p style="text-align: center;">Page 67</p> <p>1 A. That's what the application amount was 2 for, what all those dosage units compile total. 3 Q. Okay. But then when the DEA actually 4 grants the quota, it's simply an amount of that 5 API? 6 A. Yes. 7 Q. Okay. And so -- and that grant, as 8 you indicated, may -- or frequently is less than 9 the gross amount that was applied for, correct? 10 A. Correct. 11 Q. And so when that happens, do you have 12 an understanding once you have that quota grant 13 and, let's say, it's less than the gross amount 14 that was applied for, what that -- what the 15 Hobart facility is permitted to then manufacture 16 in terms of different dosages under that quota 17 grant? 18 A. So the business will decide based on 19 the demand plan and the market demand what we'll 20 make with the quota that we've been granted. 21 Q. Okay. And so is there any need to go 22 back to the DEA for any further update on the 23 quota or clarification once you make the 24 determination of what to manufacture in light of</p>	<p style="text-align: center;">Page 69</p> <p>1 A. Yes. 2 Q. Okay. And what's been your 3 involvement in that process? 4 A. As we discussed earlier, began as a 5 second set of eyes, then took on additional 6 responsibilities, and now currently I oversee 7 the person who compiles them, and I review them 8 before submission. 9 Q. Okay. In your experience, is it -- 10 what's the frequency with which there are -- 11 Mallinckrodt with respect to the Hobart facility 12 has made application for increase in quota? 13 A. Depends on the molecule. Some 14 molecules we get enough for our demand, and some 15 molecules we have to ask. Depends on the market 16 and disruptions. If another manufacturer is out 17 of supply, the distributors could be attempting 18 to get for us, so we're going to consume our 19 quota faster than anticipated. There's many 20 different factors. 21 Q. Okay. Is it -- has it ever been your 22 experience since you've been at Mallinckrodt 23 that with respect to -- well, strike that. 24 When you have worked on an application</p>

<p style="text-align: right;">Page 70</p> <p>1 for a quota increase, what are the steps that go 2 into that process? 3 A. We first take a look at what we've 4 sold versus what we need to make for the rest of 5 the year. We subtract out what we've been 6 granted, and DEA has a formula that involves 7 what you have on your end inventory, what you 8 were granted, minus what you've sold in your 9 forecast, and we will run those formulas to see 10 if we have justification to have an increase for 11 that calendar year. If a justification, meaning 12 this formula, shows that we have a shortfall and 13 that based on our sales we are entitled to more 14 quota, then we will submit a request. 15 Q. Okay. And I think you testified 16 before the break that it is sometimes the case 17 that the quota that's granted for a calendar 18 year is less than what was applied for, correct? 19 A. Yes, and many times it's less. 20 Q. Okay. And so if the quota -- let's 21 say the quota was granted for less than what was 22 applied for, and sales of that particular API 23 are consistent with what the forecast had been, 24 so as the year is unfolding, consistent with</p>	<p style="text-align: right;">Page 72</p> <p>1 A. Currently? 2 Q. Sure, start with currently. 3 A. It's in the neighborhood of six to 4 eight weeks. 5 Q. Okay. Has that changed over the 6 years? 7 A. Yes. Several years ago it was in 8 excess of 12 to 16 weeks, which is very 9 difficult on the manufacturers because of lead 10 times when we have to wait so long to get a 11 quota grant, or to even know if we're going to 12 get quota, to be able to plan our pipeline and 13 our manufacturing, so when there was greater 14 review within DEA and it could take four to six 15 -- 14 to 16 weeks. Currently we're experiencing 16 about six to eight weeks. 17 Q. And approximately what was the time 18 frame when the longer time period applied? 19 A. I don't remember the years, but it was 20 when Joe Rannazzisi was head of DEA and was 21 reviewing and signing all quota requests. 22 Q. Okay. So it was your understanding 23 there was a period of time when the actual head 24 of the DEA personally reviewed and signed off on</p>
<p style="text-align: right;">Page 71</p> <p>1 what your application originally showed, you'd 2 be running short, correct, if the quota was less 3 than what you applied for, correct? 4 A. Correct. 5 Q. And so in that situation, would you 6 apply for increased quota? 7 A. Yes. 8 Q. Okay. So it could sometimes be the 9 case that the application for increased quota 10 could show sales consistent with what had 11 previously been forecast, but the shortage 12 arising from the fact that the quota that was 13 granted was less than had been applied for? 14 A. Yes. 15 MR. O'CONNOR: Object to form. 16 BY MR. GOTTO: 17 Q. And then sometimes it may be the case 18 that sales were actually greater than what had 19 been forecast for one reason or another, and a 20 shortage from the quota results, correct? 21 A. Yes. 22 Q. Okay. In your experience, what's the 23 time frame approximately for the DEA to act on a 24 request for increased quota?</p>	<p style="text-align: right;">Page 73</p> <p>1 each quota request? 2 A. Yes. 3 Q. And do you know currently what the -- 4 who at the DEA reviews and signs off on quota 5 requests? 6 A. No, I don't. 7 MR. GOTTO: Can we go off the record 8 one second? 9 THE VIDEOGRAPHER: The time is 10 10:37 a.m., and we're off the record. 11 (Pause.) 12 THE VIDEOGRAPHER: The time is 13 10:38 a.m., and we're on the record. 14 BY MR. GOTTO: 15 Q. So, Ms. Spaulding, when -- currently 16 when there's a request for a quota increase, is 17 that typically made as to one specific API? 18 A. Each quota request is by molecule. 19 Q. Okay. And is there, in your 20 experience, is there a process of any sort of 21 interaction with the DEA when the quota request 22 is made? Is there back and forth with the DEA, 23 or do you simply wait for them to act on it and 24 see what they do?</p>

<p style="text-align: right;">Page 74</p> <p>1 MR. O'CONNOR: Object to form.</p> <p>2 A. Sometimes, sometimes, most commonly we 3 just have to wait until we receive a letter.</p> <p>4 But if DEA wants additional information, like 5 who we're selling to or detailed sales 6 information, they'll e-mail us and ask for 7 whatever additional information they want for 8 use in reviewing our request.</p> <p>9 BY MR. GOTTO:</p> <p>10 Q. Okay. And is it your experience that 11 generally do they ask for more information, or 12 is that kind of an exceptional circumstance when 13 they do that?</p> <p>14 A. It's an exception to the rule.</p> <p>15 Q. With respect to the Hobart 16 manufacturing quota, who is it at Mallinckrodt 17 that's had primary responsibility for submitting 18 the applications and any applications for 19 increased quota?</p> <p>20 A. Primary responsibility is Carrie 21 Johnson. She makes the application in the 22 database, and drafts the letters of which myself 23 and Karen review prior to submitting.</p> <p>24 Q. Okay. And who is it at Mallinckrodt</p>	<p style="text-align: right;">Page 76</p> <p>1 then Karen would be -- would review and approve.</p> <p>2 Q. Okay. So the initial, when you say 3 "the initial," you mean the calendar year 4 requests that you described was due April 1st of 5 each year?</p> <p>6 A. Yes.</p> <p>7 Q. And so what's the process that you go 8 through to compile that annual request?</p> <p>9 A. So my team will generate all of the 10 forecast data for the next year, because that's 11 all we have at that time for a future year's 12 forecast, and number of bottles to be sold, and 13 then convert that back to amount of API, and 14 account for processing waste, samples, and then 15 determine a number to meet the demand plan.</p> <p>16 Q. Okay. And when you say your team, who 17 is participating in that process?</p> <p>18 A. Carrie is the primary person.</p> <p>19 Q. And the time period during which 20 you've had that responsibility for the annual 21 quota request, what's that time period?</p> <p>22 A. When Carrie started reporting to me in 23 April of 2017.</p> <p>24 Q. Okay. Prior to that time, who was</p>
<p style="text-align: right;">Page 75</p> <p>1 that has the authority to determine the amount 2 of quota that will be requested from time to 3 time?</p> <p>4 A. I'm not sure I understand. Who is 5 signing the letters?</p> <p>6 Q. Well, that would be -- one question 7 would be who signs the letters, sure.</p> <p>8 A. Carrie Johnson is the applicator, 9 because we have log-ins with DEA, so as she's 10 the person filling in the data using her log-in 11 to DEA's database, she is the person that signs 12 the letters.</p> <p>13 Q. Okay. Does she have the authority to 14 make the decision as to the amount of quota that 15 will be requested of the DEA either in an annual 16 request or request for increase?</p> <p>17 A. No, they're all reviewed, and either 18 Karen or myself would approve them.</p> <p>19 Q. Okay. Do you have an authority to 20 approved without Ms. Harper's authorization?</p> <p>21 A. For routine requests such as the 22 initial, which there's no extraordinary 23 circumstances, yes. If there's anything 24 unusual, extraordinary, any outlying factors,</p>	<p style="text-align: right;">Page 77</p> <p>1 performing the corresponding duties with respect 2 to the annual requests?</p> <p>3 A. Karen.</p> <p>4 Q. And did you assist in that other than 5 the second pair of eyes role that you described?</p> <p>6 A. I was copied on e-mails and was 7 informed, but I didn't approve.</p> <p>8 Q. Okay. The sales -- I'm sorry. The 9 forecast data that supports the quota request, 10 how is that compiled?</p> <p>11 A. It's provided to us by our corporate 12 planning team.</p> <p>13 Q. Okay. And I think you've already 14 testified that it's often the case that the 15 quota that's actually granted by the DEA is less 16 than what's applied for, is that fair?</p> <p>17 A. Yes.</p> <p>18 Q. So would there -- would it be possible 19 to factor that in when you make the application, 20 right, apply for more than you think you might 21 need on the expectation that the DEA is going to 22 grant less than you asked for?</p> <p>23 MR. O'CONNOR: Objection to form.</p> <p>24 A. It's an estimate. It's not hard</p>

<p style="text-align: right;">Page 78</p> <p>1 numbers of what we're going to produce because 2 it's a projection. 3 BY MR. GOTTO: 4 Q. So is there any negative consequence 5 of if you were to apply for -- if you were to 6 receive quota that exceeded what you ultimately 7 turn out to need during that year, is there any 8 negative consequences to that? 9 MR. O'CONNOR: Objection to form. 10 A. I don't think I understand what you're 11 asking. 12 BY MR. GOTTO: 13 Q. Okay. Well, you make your quota 14 application for the year, and if you receive 15 quota that's less than what you actually need, 16 obviously there's a potential negative 17 consequence there that you can't fill the orders 18 that you get? 19 A. Right. 20 Q. And you have to update that and try to 21 get an increase during the year, right? That's 22 one scenario. Sounds like that's not an 23 uncommon scenario, right? 24 A. It's not. If we have excess quota at</p>	<p style="text-align: right;">Page 80</p> <p>1 say frequently. Depends on the molecule. 2 BY MR. GOTTO: 3 Q. And apart from this year-end 4 straddling you described where they allow you to 5 have a certain amount to keep your production 6 straddling the year-end, is there any carryover 7 from year to year of unused quota from one year 8 to the next? 9 A. No, absolutely not. It has to be 10 consumed by 12/31. The API has to be at your 11 facility. If it's not at your facility on 12 12/31, it's use it or lose it. 13 Q. Going back to your -- earlier today 14 you gave me a description of how your 15 responsibilities evolved over the years, and 16 we've been talking about the quota component of 17 that. You indicated that at some point you 18 became a compliance analyst, correct? 19 A. Yes, but it was a title. It wasn't -- 20 I wasn't really an analyst. That was under the 21 Tyco days, and they only had certain job 22 descriptions, so I was the only one in the 23 company who did what I did. They didn't really 24 have a job title for controlled substances</p>
<p style="text-align: right;">Page 79</p> <p>1 the end of the year, we review as part of our 2 annual process in September and October if we 3 are going to have excess quota, and we'll 4 relinquish to DEA and let them know that the 5 market has changed, or we had a project we 6 didn't need the quota for, or any number of 7 things that we're going to have excess quota. 8 Now, quota factors in a year-end 9 inventory because of timelines. If you don't 10 get your next calendar year quota on January 1, 11 you're going to be out of supply for two months 12 if you have a product that takes eight weeks to 13 make, so they allow you to have a year-ending 14 inventory so that you have API to start 15 producing to allow for continuous supply. So 16 we'll find out how much we need for a 17 year-ending inventory and what we need to meet 18 our plan, and if we have excess we'll relinquish 19 it to DEA. 20 Q. And does that happen frequently that 21 you have excess quota as you're approaching the 22 year end? 23 MR. O'CONNOR: Objection to form. 24 A. It happens occasionally. I wouldn't</p>	<p style="text-align: right;">Page 81</p> <p>1 compliance associate or coordinator, so I was 2 assigned a job title of analyst because that's 3 where I fit within their career band. 4 Q. Okay. So that was pre-'07, then, if 5 that was during the Tyco time? 6 A. Yeah, roughly. I don't remember 7 exactly, but... 8 Q. And then after Mallinckrodt spun off 9 from Tyco, what -- did you keep the compliance 10 analyst title at that point? 11 A. Under Covidien I believe I was. 12 Q. And I've seen some documents where I 13 think you signed as a compliance investigator. 14 Did you have that title at some point? 15 A. That was the initial role in 2001. I 16 was hired as a compliance investigator. Again, 17 it was a title. I would investigate losses in 18 transit, but I had many responsibilities. 19 Q. Okay. And then you indicated at some 20 point you became the senior controlled substance 21 compliance coordinator? 22 A. Yes. 23 Q. When was that? 24 A. I don't remember exactly when.</p>

Page 82	Page 84
<p>1 Q. Do you have an approximate?</p> <p>2 A. Before I was manager.</p> <p>3 Q. Okay.</p> <p>4 A. Sorry, I don't.</p> <p>5 Q. And when did you become manager?</p> <p>6 A. That, I remember, was April of 2017.</p> <p>7 Q. Okay. But in terms of title, it was</p> <p>8 compliance analyst and then compliance</p> <p>9 coordinator and then ultimately manager, is that</p> <p>10 fair?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Now, you indicated one of the</p> <p>13 things you had responsibility for are DEA</p> <p>14 audits?</p> <p>15 A. Yes.</p> <p>16 Q. Tell me what the DEA audit process is</p> <p>17 that you had responsibility with respect to.</p> <p>18 A. So when DEA came on-site to conduct an</p> <p>19 inspection, there's point of contacts that</p> <p>20 interact with the DEA, so there was -- it was</p> <p>21 typically myself and the security manager at the</p> <p>22 time were the two main points of contact with</p> <p>23 the DEA that facilitated the audit, so we would</p> <p>24 be in the front room with the DEA as they were</p>	<p>1 so I was the person pulling the records.</p> <p>2 Elizabeth McPhail would have been the front room</p> <p>3 person. And then after I started reporting to</p> <p>4 the materials manager, I became the front room</p> <p>5 person because Elizabeth McPhail was pulled out</p> <p>6 of the DEA role and I became the lead.</p> <p>7 Q. Was there a reason for that change?</p> <p>8 A. Not that I can remember specifically.</p> <p>9 Q. Do you remember approximate time frame</p> <p>10 when that occurred?</p> <p>11 A. Not exactly, no.</p> <p>12 Q. So in terms of responding to questions</p> <p>13 that the DEA would pose during these audits,</p> <p>14 what sorts of questions can you recall the DEA</p> <p>15 posing to you?</p> <p>16 A. Pretty standard audit questions, who</p> <p>17 do you use for your carrier, what is your</p> <p>18 business hours of operation, how many employees</p> <p>19 do you have, your power of attorneys, who can</p> <p>20 sign 222 forms. They have a binder of 66</p> <p>21 questions that are all specific to that license</p> <p>22 that they're auditing.</p> <p>23 Q. Okay. And were they typically things</p> <p>24 that you would be able to answer off the top of</p>
<p>1 doing their inspection, and they'd ask us for</p> <p>2 records, and we would go to our teams and get</p> <p>3 the records and bring them back. So we were</p> <p>4 considered the audit leads.</p> <p>5 Q. Okay. And who were the persons who</p> <p>6 were in the role of security manager from time</p> <p>7 to time?</p> <p>8 A. Rich Nikolaus prior to 2015, I</p> <p>9 believe, and currently Edward Egan.</p> <p>10 Q. Any other roles with respect to the</p> <p>11 DEA audits apart from this process you described</p> <p>12 of retrieving records that were requested by</p> <p>13 DEA?</p> <p>14 A. So I answered all of their questions</p> <p>15 in regards to our processes in the plant, how we</p> <p>16 handle -- facilitated the reconciliation,</p> <p>17 provided them with reports. Anytime that DEA</p> <p>18 came on-site, I was the point of contact.</p> <p>19 Whether it was for an inspection or to approve a</p> <p>20 cage or a vault or to do any type of anything on</p> <p>21 the site, I was the point of contact.</p> <p>22 Q. Okay. Does this go back to 2001 that</p> <p>23 you were the point of contact for DEA visits?</p> <p>24 A. 2001 I was what we call the back room,</p>	<p>1 your head, or normally are they things that you</p> <p>2 needed to go back and research?</p> <p>3 A. Most of the time I could answer them.</p> <p>4 I knew the processes, the plant inside and out</p> <p>5 and could answer most of their questions. If I</p> <p>6 couldn't, I didn't guess or speculate. I'd tell</p> <p>7 them I'd get the answer and get back to them.</p> <p>8 Q. And the DEA audit, is it a regularly</p> <p>9 scheduled event with a regular frequency, or was</p> <p>10 it just whenever they happen to tell you they're</p> <p>11 going to do it?</p> <p>12 A. They're typical actually unannounced,</p> <p>13 so it's whenever DEA shows up at our door. We</p> <p>14 need to be ever constantly ready for the DEA</p> <p>15 audit at any time, which we are.</p> <p>16 Q. Is it ordinarily done -- even though</p> <p>17 it may be unannounced, is it approximately an</p> <p>18 annual event, or is it done more frequently than</p> <p>19 that?</p> <p>20 A. The past audits have no rhyme or</p> <p>21 reason to any type of frequency.</p> <p>22 Q. Does the DEA after their audit provide</p> <p>23 you with any sort of report or their feedback as</p> <p>24 to the results of the audit?</p>

<p style="text-align: right;">Page 86</p> <p>1 A. There's never a DEA report. If they 2 have concerns, they will discuss them with you 3 at the time of the audit. They may direct us -- 4 they may ask us a process, and I explain it, and 5 they go, yeah, we're not comfortable with that, 6 we want you to do it this way. And so we always 7 do whatever DEA directs us because they have 8 jurisdiction over us.</p> <p>9 Q. Can you recall specific examples of 10 any sort of negative feedback you got from the 11 DEA as to a process or other matter that came up 12 in the course of their audit?</p> <p>13 MR. O'CONNOR: Objection to form.</p> <p>14 A. A negative, I'd say no. They, you 15 know, may, well, we don't really like that, or 16 we think you should do it this way, or it will 17 make it -- you know, if you give us a report in 18 this format it makes it easier for us to 19 reconcile.</p> <p>20 Negative, I don't -- I don't know what 21 would be considered negative. Any feedback they 22 gave us was always constructive.</p> <p>23 Q. Sure. Maybe negative is a bad word. 24 For example, you said they might from</p>	<p style="text-align: right;">Page 88</p> <p>1 A. Yes.</p> <p>2 Q. So in what aspects of state licensing 3 did you have responsibility for from time to 4 time at Mallinckrodt?</p> <p>5 A. I don't have any responsibility for 6 state licensing. I'm aware of it. I'd go to 7 the trainings so that we're aware of any states 8 that require us to report losses, or some states 9 have additional reporting requirements, so we 10 would attend the training to make sure we're 11 aware of any individual state requirements --</p> <p>12 Q. Okay.</p> <p>13 A. -- that may impact the site.</p> <p>14 Q. When you say "we," who else from 15 Mallinckrodt attends those types of trainings?</p> <p>16 A. It depends. So Karen Harper, my 17 manager/director will attend, and Dave Hunter 18 and myself will swap out. So we all can't leave 19 all at the same time, there's got to be somebody 20 at home, so we alternate and we'll take turns at 21 conferences. That's why, for example, when I 22 said the IQVIA conferences, you know, a half 23 dozen because we alternate years of who attends.</p> <p>24 Q. And how about, you indicated exports</p>
<p style="text-align: right;">Page 87</p> <p>1 time to time say, well, we don't really like 2 that, do it this way. Can you think of specific 3 examples where that sort of comment came back to 4 you?</p> <p>5 A. We would stage material in our 6 manufacturing hallway if it was getting ready to 7 go into production within a day, and they said, 8 well, we don't really like that, we'll let you 9 stage it for up to a shift, so then we 10 immediately changed all our processes that said 11 we couldn't stage material for any longer than a 12 shift.</p> <p>13 Q. Anything else of that nature you can 14 recall?</p> <p>15 A. We wanted to store material from our 16 manufacturing license in our distributor vault, 17 and they said, no, they wanted us to write for a 18 waiver. We couldn't -- it was -- it's in the 19 regulations that we could do it, but they asked 20 us to get a waiver on file, so we wrote for a 21 waiver on file.</p> <p>22 Q. You mentioned one of the topics that 23 you have attended trainings on is state 24 licensing?</p>	<p style="text-align: right;">Page 89</p> <p>1 was another topic that you attend trainings on 2 from time to time. What aspect of exports do 3 you have responsibility for?</p> <p>4 A. That I do have responsibility for 5 applying for the 161 application to export our 6 products, so I get the import permit from our 7 customer service department who liaisons with 8 our international customers, and then I file for 9 the export permit. When the export permit is 10 received, I notify distribution and customer 11 service that the order can be released, we have 12 the permits.</p> <p>13 Q. And you indicated the suspicious order 14 monitoring was one of the topics that you 15 attended trainings on. What aspects of 16 suspicious order monitoring do you have 17 responsibility for?</p> <p>18 A. Currently that is done by my group. I 19 have a data analyst auditor that reports to me, 20 and she is the primary contact for part of our 21 suspicious order monitoring program and our 22 anti-diversion program. She does the daily 23 orders review.</p> <p>24 Q. And who is that?</p>

Page 90	Page 92
<p>1 A. Rachelle Rogers currently.</p> <p>2 Q. And what is the aspect of the SOM</p> <p>3 program that your team has responsibility for?</p> <p>4 A. So we review the orders that are held</p> <p>5 for review that meet the algorithm criteria, we</p> <p>6 do Google searches, we do chargeback reviews, we</p> <p>7 respond to the DEA for shipping history</p> <p>8 verifications, we're in the process of</p> <p>9 transitioning the customer checklists to Hobart,</p> <p>10 off the top of my head.</p> <p>11 Q. That customer checklist transitioning,</p> <p>12 what -- it's being transitioned from where?</p> <p>13 A. It's currently residing with the --</p> <p>14 our customer data integrity group, and we're</p> <p>15 going to be reviewing them in Hobart as opposed</p> <p>16 to out at corporate.</p> <p>17 Q. And for how long has your team had</p> <p>18 these responsibilities with respect to SOM?</p> <p>19 A. Since April of 2017.</p> <p>20 Q. So before that time, what</p> <p>21 responsibilities did you have with respect to</p> <p>22 SOM?</p> <p>23 A. I was a backup reviewer to the auditor</p> <p>24 analyst who was located in St. Louis, and I was</p>	<p>1 the role, what do you mean by that?</p> <p>2 A. So when the distribution center was in</p> <p>3 St. Louis, they had a program in place, and when</p> <p>4 it moved to Hobart in 2001 that program</p> <p>5 transferred over to Hobart.</p> <p>6 Q. Okay. So there was an algorithm in</p> <p>7 place from 2001 at Hobart for SOM?</p> <p>8 A. To the best of my knowledge, yes.</p> <p>9 Q. Do you recall what that algorithm</p> <p>10 consisted of in any regard going back to 2001?</p> <p>11 A. I know it had something to do with</p> <p>12 sales history, but I don't remember the exact</p> <p>13 formula.</p> <p>14 Q. Did you have an understanding of how</p> <p>15 the algorithm changed over time?</p> <p>16 A. Not really, not until I was involved</p> <p>17 in it in 2012.</p> <p>18 Q. So since 2012, has the algorithm</p> <p>19 changed?</p> <p>20 A. Yes.</p> <p>21 Q. And have you had an understanding of</p> <p>22 how it has changed since then?</p> <p>23 A. Yes.</p> <p>24 Q. And what -- tell me what you can</p>
<p style="text-align: center;">Page 91</p> <p>1 a member of the SOM team.</p> <p>2 Q. As a backup reviewer, what was your</p> <p>3 role there?</p> <p>4 A. So if the primary reviewer was on</p> <p>5 vacation or out of the office, then I would</p> <p>6 conduct -- excuse me, I would conduct the daily</p> <p>7 reviews.</p> <p>8 Q. And what do those reviews consist of?</p> <p>9 A. Orders that have gone -- orders that</p> <p>10 have met the algorithm hit and have gone on</p> <p>11 hold, to review and determine if they're</p> <p>12 appropriate to release.</p> <p>13 Q. And when did you first have that</p> <p>14 backup responsibility?</p> <p>15 A. Roughly 2012.</p> <p>16 Q. And you've made reference a couple</p> <p>17 times to the algorithm hit. When was the</p> <p>18 algorithm implemented, do you recall?</p> <p>19 A. There's always been an algorithm in</p> <p>20 place since I went into the role. We've</p> <p>21 constantly enhanced the algorithm. But the</p> <p>22 exact formula of it, I don't remember the</p> <p>23 specifics.</p> <p>24 Q. And when you say since you went into</p>	<p style="text-align: center;">Page 93</p> <p>1 recall as to how it's changed since 2012.</p> <p>2 A. Since 2012, we were initially looking</p> <p>3 at 18-month history based on the bill to, and</p> <p>4 now we're looking at the 18-month history based</p> <p>5 on the ship to.</p> <p>6 Q. And so tell me what the difference is</p> <p>7 between bill to and ship to.</p> <p>8 A. So bill to is -- a parent company is</p> <p>9 where the bills go to, but they may have</p> <p>10 distribution centers all throughout the United</p> <p>11 States, and that's the ship to. So we bill to</p> <p>12 one location but we physically ship to another</p> <p>13 location.</p> <p>14 Q. Okay. Any other changes in the</p> <p>15 algorithm since 2012 that you're aware of?</p> <p>16 A. Not that I personally am aware of.</p> <p>17 But it was overseen by corporate, so I don't</p> <p>18 know if they may have been making changes to it</p> <p>19 or not.</p> <p>20 Q. Do you have any understanding as to</p> <p>21 the reason for the change from bill to to ship</p> <p>22 to?</p> <p>23 A. Just to always make it better and</p> <p>24 thought it would be an improvement.</p>

<p style="text-align: right;">Page 94</p> <p>1 Q. You indicated that you've been a 2 member of the SOM team. For how long have you 3 been a member of the SOM team?</p> <p>4 A. Well, I started doing the backup 5 reviews in 2012, but I don't think I was part of 6 the team until '14 or '15, right around there.</p> <p>7 Q. So is the -- was the change to the 8 algorithm that you described something that the 9 SOM team had involvement on?</p> <p>10 A. Yes.</p> <p>11 Q. Were you involved in discussions of 12 that change?</p> <p>13 A. Yes.</p> <p>14 Q. And what can you recall of those 15 discussions?</p> <p>16 A. Just that we thought it would be 17 better to see the individual distributors versus 18 the parent company to see the amounts going to 19 individual distributors for analysis purposes.</p> <p>20 Q. And do you recall why it was thought 21 that that would be better?</p> <p>22 A. Initially we thought that looking at 23 the parent company as a whole would be better, 24 because then if a distributor was shuffling</p>	<p style="text-align: right;">Page 96</p> <p>1 drug take-back boxes in our local communities 2 for the community to take back the unwanted 3 medicines. It's a comprehensive program. We 4 have disposal pouches that our government 5 regulatory affairs department has provided to 6 pharmacies and customers for people to dispose 7 of unwanted opioids.</p> <p>8 Q. To your knowledge, is there someone at 9 Mallinckrodt that has responsibility for the 10 overall comprehensive anti-diversion program?</p> <p>11 A. We all have components of it. It's 12 made up of different departments. I guess the 13 overarching would be legal, corporate legal.</p> <p>14 Q. And when you use the word "diversion," 15 what do you mean by that?</p> <p>16 A. Something taken out of the lifecycle 17 in the hands of where it doesn't belong.</p> <p>18 Q. When you say "lifecycle," what do you 19 mean?</p> <p>20 A. So we use the term analogy inside of 21 the plant where if it's not in the lifecycle, so 22 if it's not in the process of dispensing, 23 blending, compression or packaging, it's out of 24 the lifecycle.</p>
<p style="text-align: right;">Page 95</p> <p>1 between their distributions we wouldn't see it 2 if we were looking at individual distributor, 3 but by going -- looking at each distributor, 4 then we could see what we were directly shipping 5 to each location.</p> <p>6 Q. You indicated that your team currently 7 has at least some responsibility for the 8 anti-diversion program?</p> <p>9 A. Yes.</p> <p>10 Q. And what are the responsibilities 11 related to the anti-diversion program?</p> <p>12 A. So we answer any DEA or law 13 enforcement requests for shipping history 14 information through our global security 15 director. We receive -- I may receive a request 16 from a law enforcement agency for placebo 17 tablets for them to use in investigations, and I 18 will facilitate that through the global security 19 vice president. Anything that we can do to help 20 battle diversion if we're asked upon it. We 21 keep up-to-date with trends so that we have 22 knowledge and aware of what's being abused so 23 that we can pay particular attention to any 24 specific molecule, drugs of concern. We sponsor</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. So that lifecycle that you've 2 described, dispensing, blending, compression or 3 packaging, are those all things that occur in 4 the plant?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. So is diversion something that 7 occurs in the manufacturing process, as you use 8 the term?</p> <p>9 A. There's potential. We have to 10 maintain effective controls to detect diversion.</p> <p>11 Q. And what controls are in place in 12 terms of diversion in the manufacturing process?</p> <p>13 A. There's many different controls, 14 security systems, physical securities, 15 tamper-evident bags, seals, two-person 16 verifications. Every department has individual 17 procedures based on their exposure and 18 processing step.</p> <p>19 Q. Okay. And then is there diversion 20 that can occur after the product leaves the 21 manufacturing facility?</p> <p>22 A. Out of our hands?</p> <p>23 Q. Yes.</p> <p>24 A. I would say yes, there's a lot of</p>

Page 98	Page 100
<p>¹ opportunity for that.</p> <p>² Q. Okay. And some of the anti-diversion</p> <p>³ steps that you described, for example placebo</p> <p>⁴ tablets, to law enforcement, that would be</p> <p>⁵ related to diversion that's occurring after the</p> <p>⁶ product leaves your manufacturing facility,</p> <p>⁷ right?</p> <p>⁸ A. Yes.</p> <p>⁹ Q. And so diversion in that sense after</p> <p>¹⁰ it's left the manufacturing facility, when you</p> <p>¹¹ use the term diversion in that context, what</p> <p>¹² does it mean to you?</p> <p>¹³ A. Not where it belongs.</p> <p>¹⁴ Q. And you're aware that the</p> <p>¹⁵ litigation -- I realize you haven't read any of</p> <p>¹⁶ the operative complaints, but you're aware that</p> <p>¹⁷ the litigation in large part pertains to various</p> <p>¹⁸ opioids that have, to use your term, wound up</p> <p>¹⁹ not where they belong, correct?</p> <p>²⁰ A. Yes.</p> <p>²¹ Q. And you're aware that that's become a</p> <p>²² serious problem over the last period of time,</p> <p>²³ correct?</p> <p>²⁴ MR. O'CONNOR: Objection to form.</p>	<p>¹ 2012.</p> <p>² BY MR. GOTTO:</p> <p>³ Q. Do you recall any time at Mallinckrodt</p> <p>⁴ receiving any -- well, during the period that</p> <p>⁵ you reported to Ms. Harper, was there any --</p> <p>⁶ ever a time when Ms. Harper communicated to you</p> <p>⁷ that -- a belief that diversion was a serious</p> <p>⁸ problem?</p> <p>⁹ MR. O'CONNOR: Objection to form.</p> <p>¹⁰ A. She may have. I don't remember any</p> <p>¹¹ specifically.</p> <p>¹² BY MR. GOTTO:</p> <p>¹³ Q. Okay. Do you recall anyone else at</p> <p>¹⁴ Mallinckrodt at any point communicating to you a</p> <p>¹⁵ belief that diversion was a serious problem?</p> <p>¹⁶ MR. O'CONNOR: Objection to form.</p> <p>¹⁷ A. I remember potentially Bill Ratliff,</p> <p>¹⁸ who was the security director at the time,</p> <p>¹⁹ raising the concern.</p> <p>²⁰ BY MR. GOTTO:</p> <p>²¹ Q. Okay. In what context can you recall</p> <p>²² that?</p> <p>²³ A. Not specifics.</p> <p>²⁴ Q. Do you recall the approximate time</p>
<p style="text-align: center;">Page 99</p> <p>¹ A. Yes.</p> <p>² BY MR. GOTTO:</p> <p>³ Q. When do you recall first being aware</p> <p>⁴ that the diversion of opioids was a serious</p> <p>⁵ problem?</p> <p>⁶ MR. O'CONNOR: Objection to form.</p> <p>⁷ A. I don't remember exactly when I --</p> <p>⁸ when it started occurring to me.</p> <p>⁹ BY MR. GOTTO:</p> <p>¹⁰ Q. Okay. When you -- in 2001 when you</p> <p>¹¹ first had responsibility in compliance, did you</p> <p>¹² view diversion of opioids at that point as a</p> <p>¹³ serious problem?</p> <p>¹⁴ MR. O'CONNOR: Same objection.</p> <p>¹⁵ A. In 2001?</p> <p>¹⁶ BY MR. GOTTO:</p> <p>¹⁷ Q. Uh-huh.</p> <p>¹⁸ A. No, I wasn't aware of it at that time.</p> <p>¹⁹ Q. How about in 2012 when you indicated</p> <p>²⁰ you became a member of the SOM team, at that</p> <p>²¹ point did you view diversion as a serious</p> <p>²² problem?</p> <p>²³ MR. O'CONNOR: Objection.</p> <p>²⁴ A. I don't recall if I did or not in</p>	<p style="text-align: center;">Page 101</p> <p>¹ frame?</p> <p>² A. No. There was a lot going on.</p> <p>³ Q. You indicated that Mallinckrodt has a</p> <p>⁴ comprehensive program to try to address</p> <p>⁵ diversion, correct?</p> <p>⁶ A. Yes.</p> <p>⁷ Q. And so let's just talk about some of</p> <p>⁸ the components of that. One of them you</p> <p>⁹ indicated was providing placebo tablets to law</p> <p>¹⁰ enforcement, correct?</p> <p>¹¹ A. Yes.</p> <p>¹² Q. And do you recall when that began?</p> <p>¹³ A. Approximately 2016.</p> <p>¹⁴ Q. And you indicated that one of the</p> <p>¹⁵ things that's done with respect to diversion is</p> <p>¹⁶ to keep up-to-date on what the drugs of concern</p> <p>¹⁷ are, correct?</p> <p>¹⁸ A. Yes.</p> <p>¹⁹ Q. And I take it in that sense you mean</p> <p>²⁰ concern to law enforcement?</p> <p>²¹ A. Yes, and to DEA. DEA uses the</p> <p>²² terminology drugs of concern.</p> <p>²³ Q. Okay. And do you do anything</p> <p>²⁴ personally to stay up-to-date on what the drugs</p>

<p style="text-align: right;">Page 102</p> <p>1 of concern are?</p> <p>2 A. I read the DEA's web page frequently.</p> <p>3 The auditor analyst in our team does social</p> <p>4 media reviews. We benchmark amongst our team</p> <p>5 members between Webster group, St. Louis, and</p> <p>6 Hobart. If somebody sees an article that's of</p> <p>7 concern, they'll share that article so that we</p> <p>8 can keep up-to-date with what's going on.</p> <p>9 Q. Okay. And this process of being</p> <p>10 up-to-date on drugs of concern, when did that</p> <p>11 begin, at least as far as your own involvement</p> <p>12 in it?</p> <p>13 A. With the DEA conferences, that's where</p> <p>14 we would hear that terminology, and they'd say</p> <p>15 they're paying particular attention to</p> <p>16 hydrocodone because it's a drug of concern.</p> <p>17 That was a comment when the quota reviews were</p> <p>18 taking an extended amount of time, industry was</p> <p>19 asking DEA why it's taking so long, and they</p> <p>20 said they were paying particular attention to</p> <p>21 drugs of concern.</p> <p>22 Q. And when you're aware of a drug being</p> <p>23 identified as a drug of concern from time to</p> <p>24 time, what steps would that trigger at</p>	<p style="text-align: right;">Page 104</p> <p>1 were concerned about Codeine because that would</p> <p>2 remain a 3, and they were concerned that that</p> <p>3 would start replacing the hydrocodone. Most</p> <p>4 recent conference a couple years ago, they said</p> <p>5 hydromorphone 8-milligram was starting to be</p> <p>6 abused.</p> <p>7 Q. And so the drugs that you can recall</p> <p>8 being identified as drugs of concern, were they</p> <p>9 all drugs that Mallinckrodt manufactured?</p> <p>10 A. Yes.</p> <p>11 Q. And were they all drugs that</p> <p>12 Mallinckrodt had a significant market share at</p> <p>13 least of generics?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. I don't know, have any details on</p> <p>16 market share.</p> <p>17 BY MR. GOTTO:</p> <p>18 Q. Okay. Were you aware from time to</p> <p>19 time that Mallinckrodt was a leading</p> <p>20 manufacturer of many of the opioid drugs of</p> <p>21 concern that were identified from time to time?</p> <p>22 MR. O'CONNOR: Objection to form.</p> <p>23 A. No specific details. I had heard, you</p> <p>24 know, our site director refer to us as being one</p>
<p style="text-align: right;">Page 103</p> <p>1 Mallinckrodt with respect to that particular</p> <p>2 drug?</p> <p>3 A. Nothing different. We would still do</p> <p>4 all of our same processes that we always have</p> <p>5 done, it's just we were more responsive to a</p> <p>6 molecule that may be more susceptible to</p> <p>7 diversion.</p> <p>8 Q. So more sensitive to it, but how does</p> <p>9 that sensitivity manifest itself in any</p> <p>10 particular action?</p> <p>11 A. We may escalate quicker if we see a</p> <p>12 problem, or if I get a call from a law</p> <p>13 enforcement and they've expressed that they had</p> <p>14 a drug bust and it was of oxycodone, I would</p> <p>15 make sure that our security director and global</p> <p>16 VP were aware of it so that they could reach out</p> <p>17 and assist to the best of our ability.</p> <p>18 Q. So what drugs can you recall being</p> <p>19 identified as drugs of concern? You've already</p> <p>20 mentioned hydrocodone. What other ones can you</p> <p>21 recall?</p> <p>22 A. Hydrocodone, oxycodone. When DEA</p> <p>23 rescheduled hydrocodone from a C3 to a C2, they</p> <p>24 had said at one of their conferences that they</p>	<p style="text-align: right;">Page 105</p> <p>1 of the top manufacturers, but I didn't have</p> <p>2 firsthand knowledge of that.</p> <p>3 BY MR. GOTTO:</p> <p>4 Q. You've heard reference to an opioid</p> <p>5 epidemic in this country, correct?</p> <p>6 A. Yes.</p> <p>7 Q. When do you first recall being aware</p> <p>8 that there was an opioid epidemic?</p> <p>9 MR. O'CONNOR: Objection to form.</p> <p>10 A. I don't remember the exact time frame.</p> <p>11 BY MR. GOTTO:</p> <p>12 Q. Is it something that you can recall</p> <p>13 receiving any information from others at</p> <p>14 Mallinckrodt about?</p> <p>15 A. No.</p> <p>16 Q. You'd agree that certain prescription</p> <p>17 opioids manufactured by Mallinckrodt have been</p> <p>18 diverted over the years, wouldn't you?</p> <p>19 MR. O'CONNOR: Objection to form.</p> <p>20 A. Yes.</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. And you would agree that certain</p> <p>23 opioids manufactured by Mallinckrodt have</p> <p>24 contributed to the opioid epidemic, wouldn't</p>

Page 106	Page 108
<p>1 you?</p> <p>2 MR. O'CONNOR: Objection to form.</p> <p>3 A. I don't know that.</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. You indicated that one of the -- one 6 of your responsibilities has been to learn about 7 applicable regulations that apply to the Hobart 8 facility's manufacturing and distribution 9 licenses, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And do those include requirements to 12 design and maintain a suspicious order 13 monitoring program?</p> <p>14 A. Yes.</p> <p>15 Q. And so when did you first become 16 familiar with those regulatory requirements?</p> <p>17 A. So I knew that there was a system in 18 place that was being reviewed out at corporate 19 in the early 2000s, and then I recall the 20 letters to industry as calling it out 21 specifically.</p> <p>22 Q. The letters from Mr. Rannazzisi?</p> <p>23 A. Yes, from DEA.</p> <p>24 Q. Did you receive those letters when</p>	<p>1 A. No, just the early 2000s. I wouldn't 2 want to guess. I can't remember exactly.</p> <p>3 Q. All right. What would you do when 4 there was an algorithm hit that -- you indicated 5 you would review it through customer service.</p> <p>6 What were the specific steps you would take?</p> <p>7 MR. O'CONNOR: Objection to form.</p> <p>8 A. So if the order was -- on the list was 9 a clinic, and it was a higher than -- order than 10 they had been ordering historically, I would 11 contact customer service, because they had the 12 contacts with the customer, and say can you find 13 out why this customer has ordered X number of 14 bottles. And very commonly they would come back 15 and they would say, well, the customer is moving 16 and they ordered a double order to get them 17 through until they get to their new location and 18 their new 222 forms, or they were part of a 19 chain and one of their other sister clinics 20 closed so they were taking on those patients. 21 And then I would write on the list of why, and 22 I'd file it.</p> <p>23 Q. When you use the term "algorithm hit," 24 are you familiar with the term "peculiar order"?</p>
Page 107	Page 109
<p>1 they went out?</p> <p>2 A. We received two of them. There was a 3 third one that we didn't receive, like corporate 4 had it from some avenue.</p> <p>5 Q. Okay. So you were aware of corporate 6 review in the early 2000s. In terms of your -- 7 any personal involvement you had or 8 responsibility that pertained to Mallinckrodt's 9 regulatory obligation to design and maintain an 10 effective SOM program, when did you first have 11 any personal responsibility in that regard?</p> <p>12 A. So a transition between Hobart and 13 corporate a few times. There was a period, I 14 don't remember the exact years, early 2000s, of 15 which I would review the orders that were 16 algorithm hits, and if need be get additional 17 information through customer service. And then 18 there was a point in time where it had 19 transitioned back to corporate and was being 20 reviewed at the corporate level.</p> <p>21 Q. So when you -- during the period of 22 time when you had responsibility to review the 23 orders that were algorithm hits, any 24 approximation what that time period is?</p>	<p>1 A. I've heard of that before.</p> <p>2 Q. Okay. Was that a term that was part 3 of the Mallinckrodt SOM process at some point?</p> <p>4 A. Yes.</p> <p>5 Q. And so was an algorithm hit, as you've 6 used that term, the same thing as an order that 7 was identified as a peculiar order?</p> <p>8 A. Could be, yes.</p> <p>9 Q. And so if an algorithm hit order was 10 provided to you, or you became aware of it for 11 SOM purposes, and you went through customer 12 service and got an explanation and you noted 13 what that explanation was, what would happen 14 after that with respect to that particular 15 order?</p> <p>16 A. It would be released.</p> <p>17 Q. It would be filled?</p> <p>18 A. No. I apologize. So at that time 19 these were excessive order reports, so it had 20 already been shipped, and I was reviewing the 21 orders after they had been shipped.</p> <p>22 Q. Okay. So what would happen? Would 23 anything happen after that, once you got the 24 response back from customer service and you</p>

Page 110	Page 112
1 noted whatever the response was that you 2 received? Would anything further happen with 3 that order? 4 A. Those reports were sent to DEA. With 5 that order, no, nothing further would happen 6 with that order. 7 Q. Okay. But the -- there was a report 8 sent to the DEA? 9 A. Mm-hmm. 10 Q. And what was the nature of that 11 report? Was it a regular monthly report, or was 12 it a particular report with respect to each 13 order? 14 MR. O'CONNOR: Objection to form. 15 A. I don't remember if it was monthly or 16 quarterly, but it was a PDF that was sent to DEA 17 and what DEA classified and categorized as 18 excessive order reports. 19 BY MR. GOTTO: 20 Q. Okay. And was -- were you the person 21 who submitted those reports to DEA? 22 A. Yes, at that time. 23 Q. And again, do you have a time frame in 24 mind when this was the applicable procedure?	1 A. Okay. 2 Q. Do you recognize that e-mail? 3 A. No. 4 Q. Did you annually establish goals that 5 you would -- you and Ms. Harper establish what 6 your goals would be for the upcoming year? 7 A. Yes. 8 Q. Any reason to think that this e-mail 9 does not accurately describe what your goals are 10 for 2010? 11 A. No. 12 Q. Okay. And among those goals, you'll 13 see it indicates "Continue implementation and 14 ongoing upgrades of the Suspicious Order 15 Monitoring Program by second quarter fiscal year 16 '10"? 17 A. Yes. 18 Q. And the fiscal here at Mallinckrodt 19 ends when? 20 A. At this time our fiscal year was 21 October 1 through September 30 -- 30. 22 Q. Okay. So the fiscal year 2010 would 23 be the year ending September 30, 2010? 24 A. Yes.
1 A. No. I remember doing it early in my 2 career, and then it was transferred out to 3 St. Louis, out to corporate, and I -- that's why 4 I say early 2000s. It was the early part of my 5 career, but I don't remember the exact time. 6 Q. Okay. So -- 7 A. May I be excused? 8 Q. Yes. 9 MR. GOTTO: Let's go off the record. 10 THE VIDEOGRAPHER: The time is 11 11:26 a.m., and we're off the record. 12 (Whereupon, a recess was taken.) 13 THE VIDEOGRAPHER: The time is 14 11:40 a.m., and we're on the record. 15 (Whereupon, Mallinckrodt-Spaulding-1 16 was marked for identification.) 17 BY MR. GOTTO: 18 Q. Ms. Spaulding, we've handed you a 19 document that we marked as Exhibit 1 bearing 20 Bates MNK-T1_0000278740, appears to be an e-mail 21 from Karen Harper to you dated 11/11/09 22 concerning your goal. 23 Would you please take a moment to look 24 at that e-mail?	1 Q. And so the second quarter of that year 2 would have been ending on March 31, 2010, is 3 that right? 4 A. Yes. 5 Q. Do you recall what the implementation 6 and ongoing upgrades tasks were that you -- that 7 your goal included for fiscal year 2010? 8 A. No. 9 Q. Fair to say that at this point you 10 would have had an understanding of at least some 11 aspects of the SOM program at this time, 12 correct? 13 A. Some aspects, yes. 14 Q. Had you had responsibility for 15 implementation for upgrade of any aspect of the 16 SOM program for fiscal year 2009? 17 A. I don't remember. 18 Q. And do you have any recollection of 19 upgrades that you were involved in considering 20 in fiscal year 2010? 21 A. No, not any specifics. 22 Q. Do you have any recollection as to any 23 aspects of the SOM program that Ms. Harper 24 indicated to you required upgrading in this time

Page 114	Page 116
<p>1 frame?</p> <p>2 MR. O'CONNOR: Objection to form.</p> <p>3 A. Can you restate that, please?</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. Yes.</p> <p>6 Do you have any recollection of</p> <p>7 Ms. Harper in this time frame indicating to you</p> <p>8 that there were any particular aspects of the</p> <p>9 SOM program that required upgrading?</p> <p>10 A. I don't remember the specifics, no.</p> <p>11 Q. Do you have a general understanding of</p> <p>12 what required upgrading?</p> <p>13 A. No.</p> <p>14 Q. Do you recall if there was a written</p> <p>15 SOM program at this point?</p> <p>16 A. What do you mean by "written"?</p> <p>17 Q. Well, was there a SOM program that was</p> <p>18 memorialized in any sort of document?</p> <p>19 A. Oh, an SOP?</p> <p>20 Q. Well, or any sort of document.</p> <p>21 A. Not at this time. I don't remember</p> <p>22 what was in place at this time.</p> <p>23 Q. Okay. You don't recall one way or the</p> <p>24 other whether there was a written program or</p>	<p>1 '10 Assessment.</p> <p>2 Would you take a look at that document</p> <p>3 and tell me if you recognize it?</p> <p>4 (Witness reviewing document.)</p> <p>5 A. This is my year-end review for fiscal</p> <p>6 year '10.</p> <p>7 Q. Okay. Did you receive a similar</p> <p>8 review each year?</p> <p>9 A. There's a review done each year, it's</p> <p>10 not -- it's a different software program, but</p> <p>11 yes, there's a review done each year.</p> <p>12 Q. Okay. If you would turn to the page</p> <p>13 that's numbered 5, it ends in Bates 708. And</p> <p>14 the Performance Factor or Target Competency is</p> <p>15 "DEA Reports."</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And in the Expected Results</p> <p>19 paragraph, the last sentence says "Continue</p> <p>20 implementation and ongoing upgrades of the</p> <p>21 Suspicious Order Monitoring Program by second</p> <p>22 quarter fiscal year '10."</p> <p>23 That's what we had seen in the prior</p> <p>24 document, correct, your goals for fiscal year</p>
<p>1 not?</p> <p>2 A. I don't.</p> <p>3 Q. Do you recall working with anyone in</p> <p>4 fiscal year '10 on the implementation and</p> <p>5 upgrading of the SOM?</p> <p>6 A. In fiscal year '10. I know there was</p> <p>7 a review of the program done. I don't know what</p> <p>8 year it was.</p> <p>9 Q. Okay. Who can you recall being</p> <p>10 involved in that review?</p> <p>11 A. Karen Harper.</p> <p>12 Q. Anyone else?</p> <p>13 A. There would have been other</p> <p>14 stakeholders of the business, but I don't</p> <p>15 remember the specific people.</p> <p>16 Q. And you don't recall what the time</p> <p>17 frame was of that review?</p> <p>18 A. No.</p> <p>19 (Whereupon, Mallinckrodt-Spaulding-2</p> <p>20 was marked for identification.)</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. We've handed you what we've marked as</p> <p>23 Exhibit 2, a multi-page document beginning at</p> <p>24 MNK-T1_0000490704, appears to be a Fiscal Year</p>	<p>1 '10?</p> <p>2 A. Yes.</p> <p>3 Q. Now, that was -- was that upgrade</p> <p>4 accomplished in fiscal year '10?</p> <p>5 A. I don't remember what the upgrade was</p> <p>6 to know whether it was completed that year or</p> <p>7 not.</p> <p>8 Q. So in your "End-of-Year</p> <p>9 Accomplishments (Employee)" paragraph, the last</p> <p>10 sentence indicates "Continuing to assist and</p> <p>11 implement upgrades on the SOM when identified</p> <p>12 along with generation of a quarterly report to</p> <p>13 DEA."</p> <p>14 Do you see that?</p> <p>15 A. No. I'm sorry. Which one? Under</p> <p>16 that same one?</p> <p>17 Q. Sure. Yes, "End-of-year</p> <p>18 Results/Accomplishments (Employee)," the</p> <p>19 paragraph that begins "All controlled substance</p> <p>20 reports."</p> <p>21 A. Okay. My -- that was my feedback.</p> <p>22 Okay. I'm sorry.</p> <p>23 Q. It's the last sentence of that</p> <p>24 paragraph.</p>

Page 118	Page 120
<p>1 A. Yes.</p> <p>2 Q. Okay. And then if you look at the 3 following paragraph "End-of-Year 4 Results/Accomplishments (Manager)," would that 5 have been Ms. Harper preparing that?</p> <p>6 A. Yes. So the employee was my -- my 7 review of my work throughout the year, and then 8 the next one was Karen's, yes.</p> <p>9 Q. Okay. And under the manager 10 paragraph, the last sentence reads "Eileen 11 volunteered for extra responsibility within the 12 Suspicious Order Monitoring Program in fiscal 13 year '10, enhancements to the system and 14 expansion of Eileen's role will be accomplished 15 in fiscal year '11."</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. And so does that indicate that the -- 19 whatever the upgrades were that were the subject 20 of your goal for fiscal year '10 were not 21 actually implemented in fiscal year '10, 22 correct?</p> <p>23 MR. O'CONNOR: Objection to form.</p> <p>24 A. I don't know that.</p>	<p>1 submitted to DEA.</p> <p>2 Q. And so was that a report you were 3 submitting in fiscal year 2010?</p> <p>4 A. I don't remember. "When identified 5 along with generation of quarterly report."</p> <p>6 Q. Well, you make reference under your 7 accomplishments to generation of a quarterly 8 report to DEA, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And that quarterly report would be the 11 algorithm hit or peculiar order hit report that 12 you testified to earlier today, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Do you know if any orders were 15 identified as suspicious orders in fiscal year 16 2010 by Mallinckrodt?</p> <p>17 A. No, I don't know.</p> <p>18 Q. Can you recall at any time during your 19 time at Mallinckrodt an order being reported to 20 the DEA by Mallinckrodt as a suspicious order?</p> <p>21 A. Yes.</p> <p>22 Q. When can you recall that?</p> <p>23 A. I don't know when it was for. I don't 24 know when it was reported.</p>
<p style="text-align: center;">Page 119</p> <p>1 BY MR. GOTTO:</p> <p>2 Q. Okay. Well, there's nothing either in 3 your -- the employee end-of-year 4 results/accomplishments or the manager 5 end-of-year accomplishments that indicates that 6 those upgrades were completed in 2010, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And the manager comments indicate that 9 there will be enhancements and expansion of your 10 role accomplished in fiscal year '11 -- 2011, 11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. Do you recall what those enhancements 14 to the system or expansion of your role were in 15 2011?</p> <p>16 A. No.</p> <p>17 Q. Under the paragraph -- the employee 18 feedback paragraph, at the very end there's 19 reference to quarterly report to the DEA.</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. What was that quarterly report?</p> <p>23 A. So that was the algorithm hits for 24 each month combined by quarter and then</p>	<p style="text-align: center;">Page 121</p> <p>1 Q. Do you recall any details about the 2 order?</p> <p>3 A. Yes, it was for fentanyl that was 4 going to a veterinary clinic or a veterinarian.</p> <p>5 Q. Okay. And was this a single incident?</p> <p>6 A. That I was aware of. I don't -- there 7 was others that were part of the program, and 8 monitoring, they may have reported.</p> <p>9 Q. Okay. As far as your own personal 10 knowledge, you're only aware of the one, right?</p> <p>11 A. Yes.</p> <p>12 Q. And in terms of have you heard of 13 others at Mallinckrodt -- other than things 14 you've had personal involvement with, have you 15 heard of other orders that Mallinckrodt reported 16 to DEA as suspicious orders?</p> <p>17 A. I don't recall.</p> <p>18 Q. Okay.</p> <p>19 (Whereupon, Mallinckrodt-Spaulding-3 20 was marked for identification.)</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. We've marked as Exhibit 3 a two-page 23 document bearing a Bates MNK-T1_000702654.</p> <p>24 Would you take a moment to look at those</p>

Page 122	Page 124
<p>1 e-mails, please?</p> <p>2 (Witness reviewing document.)</p> <p>3 A. Okay.</p> <p>4 Q. Do you recognize those e-mails?</p> <p>5 A. No.</p> <p>6 Q. Okay. These refer to a midyear</p> <p>7 assessment done in April of 2011, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Was that a normal process at</p> <p>10 Mallinckrodt, that you would receive a midyear</p> <p>11 assessment of your performance?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. The e-mail from Ms. Harper on</p> <p>14 April 7th of 2011 indicates that you took the</p> <p>15 lead in auditing Cedardale distributor after the</p> <p>16 program identified that customer as distributing</p> <p>17 excessive amounts of oxycodone into the State of</p> <p>18 Florida, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And that you proofread and edited the</p> <p>21 three revised SOPs related to SOM, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Do you recall the Cedardale audit</p> <p>24 that's referred to?</p>	<p>1 just show up? How did it come to be?</p> <p>2 A. It was scheduled.</p> <p>3 Q. And how did you know what procedures</p> <p>4 to follow in conducting that audit?</p> <p>5 A. So what our process was, or -- so we</p> <p>6 -- just through conducting audits, learning from</p> <p>7 DEA what were drugs of concern, we went and</p> <p>8 reviewed their SOM program.</p> <p>9 Q. Okay. Well, let me back up.</p> <p>10 Had you conducted other audits of</p> <p>11 distributors prior to this one?</p> <p>12 A. No.</p> <p>13 Q. Okay. And had you participated in any</p> <p>14 audits of distributors prior to this one?</p> <p>15 A. I hadn't participated in on-site</p> <p>16 audits, no.</p> <p>17 Q. Okay. So how did you know what to do</p> <p>18 as part of the audit if you hadn't done one</p> <p>19 before or participated in an on-site audit?</p> <p>20 A. So we had -- we've had collaboration</p> <p>21 calls with distributors that I had been on, and</p> <p>22 had heard the questions that the compliance</p> <p>23 manager and the security director from corporate</p> <p>24 had been asking. We had a checklist that we</p>
<p style="text-align: center;">Page 123</p> <p>1 A. Yes.</p> <p>2 Q. What can you recall about that audit?</p> <p>3 A. The security manager and myself went</p> <p>4 to Cedardale in New Jersey to perform an on-site</p> <p>5 audit of their -- it's more a collaboration</p> <p>6 visit just to review their SOM program.</p> <p>7 Q. And what triggered that audit?</p> <p>8 A. A report that Karen had in which she</p> <p>9 saw a high amount of oxycodone, or the team saw</p> <p>10 a high amount of oxycodone going into the State</p> <p>11 of Florida.</p> <p>12 Q. Okay. And who was the security</p> <p>13 manager who performed that audit with you?</p> <p>14 A. Rich Nikolaus.</p> <p>15 Q. And I take it that was an on-site</p> <p>16 audit of Cedardale's facility?</p> <p>17 A. Yes.</p> <p>18 Q. Had you been to that facility</p> <p>19 previously?</p> <p>20 A. No.</p> <p>21 Q. Had you had any interaction with the</p> <p>22 people at Cedardale prior to your audit?</p> <p>23 A. No.</p> <p>24 Q. Was the audit scheduled, or did you</p>	<p style="text-align: center;">Page 125</p> <p>1 used to prompt questions. We knew what our own</p> <p>2 program was at the time. We had gone to</p> <p>3 trainings and had -- from DEA and who had said</p> <p>4 from the pulpit that, for example, thresholds</p> <p>5 are not acceptable as a stand-alone SOM program,</p> <p>6 that's not an indicator of a good program if</p> <p>7 it's only based on threshold quantities.</p> <p>8 Q. What does that mean, threshold</p> <p>9 quantities?</p> <p>10 A. So a certain limit, they can order up</p> <p>11 to X amount, and then after that amount, say,</p> <p>12 per month, the first and the next month they</p> <p>13 could order that amount again.</p> <p>14 Q. Okay. Were there particular concerns</p> <p>15 regarding Cedardale that you wanted to be sure</p> <p>16 you addressed as part of this audit?</p> <p>17 A. Well, as a result of whatever the team</p> <p>18 had discovered, we were wanting to confirm if</p> <p>19 they did, in fact, have large amount of</p> <p>20 oxycodone going into Florida.</p> <p>21 Q. Okay. And so what steps did you take</p> <p>22 to try to confirm that?</p> <p>23 A. We just spoke to them. It was all</p> <p>24 reliable -- relied on them describing. We</p>

Page 126	Page 128
<p>1 didn't review their records or their policies.</p> <p>2 We'd ask them if they had policies in place, but</p> <p>3 we didn't approve or condone or authorize an SOM</p> <p>4 program.</p> <p>5 Q. Okay. Did you -- did they have a</p> <p>6 written SOM program that you reviewed?</p> <p>7 A. Not that I can recall.</p> <p>8 Q. But they described to you what their</p> <p>9 SOM program was?</p> <p>10 A. Yes.</p> <p>11 Q. And what can you recall the</p> <p>12 description?</p> <p>13 A. That it was primarily based on these</p> <p>14 threshold quantities which DEA had said from the</p> <p>15 pulpit was not sufficient enough.</p> <p>16 Q. Okay. And so when you can recall DEA</p> <p>17 saying that the threshold quantity approach was</p> <p>18 not sufficient, did they give any indication of</p> <p>19 what additional components an SOM program should</p> <p>20 contain beyond threshold quantities?</p> <p>21 A. No. There's been very lack of</p> <p>22 guidance from DEA around suspicious order</p> <p>23 monitoring and what is good and what is not</p> <p>24 good. They would tell us things to be aware of</p>	<p>1 non-controls, their amount of cash versus</p> <p>2 non-cash, their demographics around the area to</p> <p>3 know whether the quantities that they're</p> <p>4 shipping to the pharmacy are justified or not.</p> <p>5 Q. In the audit you did of Cedardale, did</p> <p>6 you take any steps to identify who any specific</p> <p>7 customers of Cedardale were?</p> <p>8 A. I don't remember if we had specific</p> <p>9 names or not.</p> <p>10 Q. I take it that the focus of the audit</p> <p>11 was this question of whether Cedardale was</p> <p>12 distributing excessive oxycodone to Florida,</p> <p>13 correct?</p> <p>14 A. Yes, because we're concerned about our</p> <p>15 direct customers, and we were trying to make</p> <p>16 sure they had a robust program in place.</p> <p>17 Q. Okay. At this time -- well, let me</p> <p>18 ask you, do you recall when the Cedardale audit</p> <p>19 was conducted?</p> <p>20 A. Early 2011.</p> <p>21 Q. Okay. At that time did you have any</p> <p>22 information with respect to the identity of any</p> <p>23 of Cedardale's customers?</p> <p>24 A. I don't remember if I did or didn't.</p>
<p>Page 127</p> <p>1 such as red flags, but they wouldn't tell us</p> <p>2 what makes a good program or what doesn't make a</p> <p>3 good program, only to be aware of.</p> <p>4 Q. Okay. So when you conducted the audit</p> <p>5 at Cedardale, their SOM program as they</p> <p>6 described it to you simply consisted of this</p> <p>7 kind of threshold quantity limit that DEA had</p> <p>8 specifically said was inadequate, is that fair?</p> <p>9 A. Yes.</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. Yes.</p> <p>12 BY MR. GOTTO:</p> <p>13 Q. Okay. And did you tell them that,</p> <p>14 that your understanding from DEA was that that</p> <p>15 was not an adequate?</p> <p>16 A. We did coach them in that they should</p> <p>17 have more around their program than just a</p> <p>18 threshold quantity amount, and that they should</p> <p>19 be looking at their pharmacies holistically in</p> <p>20 doing on-site inspections. It was a</p> <p>21 recommendation.</p> <p>22 Q. When you say "looking at a pharmacy</p> <p>23 holistically," what do you mean by that?</p> <p>24 A. Their amount of controls versus</p>	<p>Page 129</p> <p>1 Q. Do you recall at any point seeing any</p> <p>2 reports of analysis of chargeback data that</p> <p>3 contained information with respect to the</p> <p>4 ultimate -- with respect to the customers of</p> <p>5 Mallinckrodt's customers in 2010 or 2011?</p> <p>6 A. I remember that there was three</p> <p>7 customers that we as an SOM team decided that</p> <p>8 needed to be audited. I don't remember the</p> <p>9 specifics behind it.</p> <p>10 Q. Okay. Do you remember who those three</p> <p>11 customers were?</p> <p>12 A. Masters and KeySource in Cedardale.</p> <p>13 Q. Do you recall seeing a report at any</p> <p>14 time in 2010 that identified customers who</p> <p>15 ordered controlled substances from multiple</p> <p>16 Mallinckrodt distributors?</p> <p>17 A. No.</p> <p>18 Q. Do you recall being aware of the</p> <p>19 existence of such a report?</p> <p>20 A. Yes. I think there was something that</p> <p>21 prompted the team to review those three</p> <p>22 customers.</p> <p>23 Q. And do you know if that report</p> <p>24 regarding customers that ordered from multiple</p>

Page 130	Page 132
<p>1 Mallinckrodt distributors, do you know if that 2 was generated through an analysis of chargeback 3 data?</p> <p>4 A. I don't. Don't remember.</p> <p>5 Q. Do you know who Kate Mellencamp was, 6 or Kate Neely? I think it was the same person.</p> <p>7 A. Yeah, I remember the name. I don't 8 remember the role.</p> <p>9 Q. Okay. How about Ginger Collier?</p> <p>10 A. Yes, Ginger I remember.</p> <p>11 Q. And who was she?</p> <p>12 A. She was in marketing.</p> <p>13 Q. Do you recall if Ms. Collier or 14 Ms. Mellencamp had any role in developing this 15 report on multiple orders from multiple 16 distributors?</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. I don't remember specifically 19 anything.</p> <p>20 BY MR. GOTTO:</p> <p>21 Q. Okay. And so when you conducted the 22 audit at Cedardale, were you aware of whether 23 any of Cedardale's customers had been identified 24 as parties who ordered from multiple</p>	<p>1 3, not 2, 3 indicates that you proofread and 2 edited the three revised SOPs related to SOM. 3 And again, this is April, 2011. Do you recall 4 those three revised SOPs?</p> <p>5 A. Not which specific SOPs they are.</p> <p>6 Q. Do you recall the subject matter of 7 what was addressed in any of those -- by any of 8 those revised SOPs?</p> <p>9 A. Well, we have three SOPs that apply to 10 suspicious order monitoring. I'm not sure that 11 those are the three SOPs that we're talking 12 about.</p> <p>13 Q. So the SOPs that apply to SOM, what 14 are the subject matters that they cover?</p> <p>15 A. One, how to do the review of the 16 algorithm hits. And I don't remember exactly 17 what the other two are, not definitely.</p> <p>18 Q. And when did these SOPs come into 19 existence, as far as you know?</p> <p>20 A. They were drafted by the SOM team and 21 reviewed, so whenever that team took it back 22 from Hobart and was reviewing the program. I 23 don't remember. It was before 2011, obviously, 24 but I don't remember when.</p>
<p style="text-align: center;">Page 131</p> <p>1 Mallinckrodt distributors?</p> <p>2 A. I don't remember anything about 3 knowing their pharmacies, knowing who they were 4 supplying.</p> <p>5 Q. What was the -- what can you recall 6 about the results of the Cedardale audit?</p> <p>7 A. I remember that we were not 8 comfortable that they had a robust enough 9 program in place.</p> <p>10 Q. Okay. And as a result, was Cedardale 11 cut off from -- as a Mallinckrodt distributor?</p> <p>12 A. I recall that they were -- we stopped 13 shipping to them. I don't recall if it was 14 before the audit or not, or a result of the 15 audit.</p> <p>16 Q. And do you know if Mallinckrodt ever 17 resumed shipping to Cedardale after that?</p> <p>18 A. I believe we did with some 19 restrictions.</p> <p>20 Q. Do you know what the restrictions 21 were?</p> <p>22 A. C3 through 5 only. We didn't resume 23 shipping C2s.</p> <p>24 Q. Exhibit 2 also indicates -- I'm sorry,</p>	<p style="text-align: center;">Page 133</p> <p>1 Q. Okay. 2 (Whereupon, Mallinckrodt-Spaulding-4 3 was marked for identification.)</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. We've marked as Exhibit 4 a multi-page 6 document beginning at Bates MNK-T1_0007730928. 7 Appears to be an e-mail thread from 2013 between 8 you and Ms. Harper. Would you take a moment to 9 look at that, and tell me if you recognize it. 10 (Witness reviewing document.)</p> <p>11 Q. Feel free to look at whatever you 12 want, my only question is on the first page of 13 that document.</p> <p>14 A. Okay. 15 (Witness reviewing document.)</p> <p>16 Q. Do you recognize that document?</p> <p>17 A. No, not exactly.</p> <p>18 Q. Okay. On the first page, the e-mail 19 from you to Ms. Harper, October of 2013, any 20 reason to doubt that you sent this e-mail?</p> <p>21 A. No.</p> <p>22 Q. Okay. Under "Suspicious Order 23 Monitoring" in the middle of the page, do you 24 see that?</p>

Page 134	Page 136
1 A. Yes. 2 Q. "Description. Support Legal 3 Department Regulatory Compliance in the arena of 4 interaction with the Drug Enforcement 5 Administration by managing and coordinating 6 enhancements with the SOM program." 7 Do you see that? 8 A. Yes. 9 Q. Do you recall the enhancements to the 10 SOM program that you managed or coordinated in 11 this time frame? 12 A. No, we were always constantly trying 13 to change it, make it better, so I don't 14 remember what in specific. 15 Q. Okay. The next paragraph says "Ensure 16 all orders placed on SOM hold are reviewed 17 thoroughly and accurately to ensure SOM DEA 18 Compliance." 19 In this time frame in 2013, who was 20 involved in the review of orders that were 21 placed on SOM hold? 22 A. Jen Buist, but I don't know when she 23 came on board. 24 Q. And what department did she work in?	1 sentence? 2 A. We had a very intensive DEA inspection 3 that year. 4 Q. Okay. And what aspects of the 5 inspection were particularly intensive, as you 6 can recall? 7 A. Just there was many investigators 8 there for six weeks. 9 Q. Did that investigation extend to any 10 aspects of the SOM program? 11 A. Yes. 12 Q. In what regard can you recall them 13 interacting with you with respect to SOM? 14 A. They were asking us about our SOM 15 program in which we, as did any other audit, 16 would explain the program at that time. 17 Q. Do you recall if DEA identified to you 18 any shortcomings or criticisms of the SOM 19 program? 20 A. Not that I remember. 21 (Whereupon, Mallinckrodt-Spaulding-5 22 was marked for identification.) 23 BY MR. GOTTO: 24 Q. We've marked as Exhibit 5 a two-page
1 A. She was under government compliance at 2 that time. 3 Q. So was she the person who would review 4 an order that was placed on hold to determine 5 whether the order would be released? 6 A. Yes. 7 Q. And so in terms of your ensuring that 8 orders were thoroughly and accurately reviewed, 9 did you interact with her? 10 A. She -- if she was unsure of an order 11 and wanted to know some supporting data, she 12 would reach out to me. But I was the backup at 13 this time. So it's referring to any order that 14 I reviewed. 15 Q. Okay. But she had the ability to 16 review and release an order without consulting 17 with you, is that correct? 18 A. Yes. 19 Q. The next paragraph under "Employee 20 Evaluation" says "Fiscal year '13 has been a 21 challenging year for the Hobart site from the 22 Controlled Substances Compliance aspect." 23 What can you recall that made fiscal 24 year '13 a challenging year as you state in that	1 document beginning at Bates MNK-T1_0000274080, 2 an e-mail dated -- well, series of e-mails dated 3 May of 2008. Would you take a moment to look at 4 those e-mails, please? 5 (Witness reviewing document.) 6 Q. Do you recognize those e-mails? 7 A. No. 8 Q. Okay. The May 12th e-mail from 9 Ms. Harper indicates that she's gathered a group 10 consisting of a few persons that she identifies 11 to review the suspicious order monitoring 12 program with the goal of making it more robust 13 in light of DEA activity, and she asks if you 14 would be willing to review a draft procedure and 15 serve on the team as a Hobart advisor. 16 Do you see that? 17 A. Yes. 18 Q. And do you recall her making that 19 request to you in 2008? 20 A. Based on -- only based on this e-mail. 21 I don't recall it. 22 Q. All right. And then you respond 23 "Absolutely - currently at DEA conference," 24 correct?

Page 138	Page 140
<p>1 A. Yes.</p> <p>2 Q. And no reason to doubt that you sent</p> <p>3 that e-mail, correct?</p> <p>4 A. No.</p> <p>5 Q. Okay. In Ms. Harper's e-mail under</p> <p>6 the dashed lines there are -- as an aside, she</p> <p>7 mentions in a conference she attended "among the</p> <p>8 agenda items was Suspicious Order Monitoring."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And "Other suggestions included," she</p> <p>12 states, "On-site visits for all controlled</p> <p>13 substance customers; Close scrutiny of small,</p> <p>14 independent pharmacies; Close scrutiny of pain</p> <p>15 management clinics."</p> <p>16 Are any of those three steps anything</p> <p>17 that you can recall being implemented at</p> <p>18 Mallinckrodt in this time frame in 2008?</p> <p>19 A. In 2008, no.</p> <p>20 Q. Do you recall when any of those steps</p> <p>21 were implemented at Mallinckrodt?</p> <p>22 A. We started on-site visits of</p> <p>23 controlled substance customers in 2010, '11 with</p> <p>24 the KeySource, Masters, and Cedardale that we</p>	<p>1 that the SOM program that was in place at</p> <p>2 Mallinckrodt complied with DEA requirements?</p> <p>3 A. Based on the knowledge we had at that</p> <p>4 time, yes.</p> <p>5 Q. Did there come a time when you had an</p> <p>6 understanding that the SOM program in place at</p> <p>7 Mallinckrodt did not comply with DEA</p> <p>8 requirements?</p> <p>9 A. No.</p> <p>10 (Whereupon, Mallinckrodt-Spaulding-6</p> <p>11 was marked for identification.)</p> <p>12 BY MR. GOTTO:</p> <p>13 Q. Exhibit 6 is a lengthy document</p> <p>14 beginning at Bates MNK-T1_0005187729. It's an</p> <p>15 e-mail attaching a PowerPoint presentation, the</p> <p>16 first page of which contains your name.</p> <p>17 It's a lengthy document, I can direct</p> <p>18 you to a few pages that I have some questions</p> <p>19 for you on rather than have you review the</p> <p>20 entire document. But certainly feel free to</p> <p>21 look at any part of it that you need to to</p> <p>22 answer any of my questions.</p> <p>23 Do you recall what the purpose of this</p> <p>24 document was?</p>
<p>1 spoke of.</p> <p>2 Q. Okay. In Ms. Harper's e-mail to you,</p> <p>3 she identifies a goal of making the SOM program</p> <p>4 more robust. Do you recall what the SOM program</p> <p>5 consisted of in May of 2008?</p> <p>6 A. Not exactly, no.</p> <p>7 Q. Do you have a general recollection?</p> <p>8 A. Generally it was just the algorithm.</p> <p>9 Q. And do you recall what the components</p> <p>10 of the algorithm were at this point?</p> <p>11 A. Only one of them. That was based on</p> <p>12 their previous order history.</p> <p>13 Q. Would that be the sort of threshold</p> <p>14 metric that you understood the DEA said was</p> <p>15 inadequate?</p> <p>16 MR. O'CONNOR: Objection to form.</p> <p>17 A. No. So a threshold is when you say,</p> <p>18 okay, they can only order up to 5,000 dosage</p> <p>19 units a month. This was based on what they</p> <p>20 historically had been ordering to know that --</p> <p>21 whether they were continuing to order in</p> <p>22 historical patterns.</p> <p>23 BY MR. GOTTO:</p> <p>24 Q. So was it your understanding in 2008</p>	<p>1 A. Yes.</p> <p>2 Q. What was it?</p> <p>3 A. It's what we used for training new</p> <p>4 employees when they started.</p> <p>5 Q. Okay. And just for the record, the</p> <p>6 cover e-mail is dated January of 2011, correct?</p> <p>7 A. Yes.</p> <p>8 Q. And did you prepare the portion of the</p> <p>9 presentation that's the slides that are behind</p> <p>10 your name?</p> <p>11 A. It was a combination of Karen Harper</p> <p>12 and myself.</p> <p>13 Q. Okay. If you turn to the page --</p> <p>14 unfortunately these are not numbered. Let me</p> <p>15 just count pages for you, 1, 2, 3, 4, 5, 6, 7,</p> <p>16 the eighth page in, there's "Statistics on</p> <p>17 National Drug Abuse Trends."</p> <p>18 Do you see that?</p> <p>19 A. "DEA Regulatory Authority" up on the</p> <p>20 top?</p> <p>21 Q. Well, it's immediately behind the</p> <p>22 slide that says "Security & Controlled Substance</p> <p>23 Compliance."</p> <p>24 A. Oh, yes. Okay.</p>

Page 142	Page 144
<p>1 Q. So there's "Statistics on National 2 Drug Abuse Trends," and the following slide is 3 "Abuse Trends." Why was it important to give 4 this information to new hires in their training? 5 A. Because we wanted them to understand 6 why we have these security policies and 7 procedures around our processes, and why two 8 people have to be present at all times. 9 Q. Okay. And so the page -- the slide, I 10 think, the next one after the one you're on, 11 there you go, "Abuse Trends," identifies certain 12 statistical items such as "estimated 48 million 13 people have used prescription drugs for 14 non-medical reasons in their lifetimes." These 15 abuse trends were something that Mallinckrodt 16 tracked at the time, correct? 17 A. No. This is information that we 18 gleaned off of either DEA's website or NIDDA's 19 website. 20 Q. Okay. The following slide, "DEA 21 reiterates responsibilities." Do you see that 22 one? 23 A. Yes. 24 Q. And on this slide you make reference</p>	<p>1 against a registrant and their registration 2 regardless of who you are. 3 Q. All right. You can put that aside. 4 (Whereupon, Mallinckrodt-Spaulding-7 5 was marked for identification.) 6 BY MR. GOTTO: 7 Q. We've marked as Exhibit 7 a multi-page 8 document beginning at Bates MNK-T1_0000448773. 9 It's entitled "oxycodone Extended Release Risk 10 Map Action Plan." Let's take a look at that 11 document, and tell me if you recognize it. 12 A. No. 13 Q. You don't recall ever seeing this 14 before? 15 A. No, I don't remember it. 16 Q. Are you familiar with the -- with 17 Mallinckrodt having a risk map action plan with 18 respect to various products? 19 A. I'm aware that some products require 20 risk map programs. 21 Q. Okay. And do you know which products 22 require those programs? 23 A. Oxycodone ER was one of them. There's 24 several others, but I don't know them</p>
<p>1 to certain statements made by DEA in 2 correspondence to Mallinckrodt, correct? 3 A. Yes. 4 Q. Are these items of correspondence 5 the -- two of the items you referred to earlier 6 today in your testimony, letters from DEA? 7 A. The one letter is. I don't recall the 8 one that was specific for Mark Coverly. 9 Q. Okay. The one on the right from 10 Mr. Rannazzisi? 11 A. Yes. 12 Q. The following slide "Recent DEA 13 Actions Involving Distributors" which talks 14 about actions involving AmerisourceBergen, 15 Cardinal, and McKesson, why was it important to 16 provide that information to new hires? 17 A. Because we wanted them to understand 18 the importance of having a DEA license. 19 Q. And then the following several slides 20 involve specific examples, Masters 21 Pharmaceutical, Rite Aid Issues, CVS Fines. Why 22 was it important to provide that information to 23 new hires? 24 A. To show them that DEA can take action</p>	<p>143</p> <p>1 specifically. 2 Q. And do you know why oxycodone requires 3 a risk map action plan? 4 A. No, that's an FDA requirement. 5 Q. Do you know if Mallinckrodt had any 6 other -- Mallinckrodt manufactured any other 7 opioid other than oxycodone that required a risk 8 map action plan? 9 A. Yes, there were others, but I don't 10 remember specifically which products. 11 Q. Did you have any involvement in the 12 preparation of the Oxycodone ER risk map action 13 plan? 14 A. I don't remember it, so I'm not sure. 15 Q. Okay. If you turn to Page 3 of the 16 document ending in Bates 775, under "Supply 17 Chain & Security," you see your name appears on 18 several of the entries. 19 Do you see that? 20 A. Yes. 21 Q. So one entry, "Provide notification to 22 DEA of any confirmed diversion," and you're one 23 of the persons responsible there, correct? 24 A. Yes.</p>

Page 146	Page 148
<p>1 Q. Do you ever recall that occurring, 2 that you provided notification to DEA of any 3 confirmed diversion? 4 A. No, that would have been a 106 form. 5 Q. And do you recall ever providing a 106 6 form to DEA confirming diversion on oxycodone? 7 A. Oxycodone, or Oxycodone ER? 8 Q. Oxycodone ER, I'm sorry. 9 A. No, not without looking at my records. 10 Q. Next item is "Notify Covidien 11 management...of suspected diversion." 12 Do you see that? 13 A. Yes. 14 Q. Do you recall ever doing that 15 notification of Covidien management of suspected 16 diversion of Oxycodone ER? 17 A. No, I don't remember. 18 Q. On the next page, Page 4, the -- one, 19 two, three -- fourth item down, "Photographs of 20 drivers authorized to handle controlled 21 substances are maintained on file at the 22 distribution center." Is that something that 23 was done at Hobart? 24 A. Yes.</p>	<p>1 Q. Okay. Do you interact with 2 Mr. Gillies? 3 A. Yes. 4 Q. In what capacities? 5 A. I escalate to him any law enforcement 6 inquiries for either law information or the 7 placebos as we talked about earlier, and if he 8 contacts me for information, I provide it. 9 Q. Have you ever had any -- has 10 Mr. Gillies ever expressed any dissatisfaction 11 with your work product? 12 A. Not that I can recall. 13 Q. Have you had any difficulties in 14 interacting with Mr. Gillies over the years? 15 A. No. 16 MR. GOTTO: Let's go off the record. 17 THE VIDEOGRAPHER: The time is 18 12:32 p.m., and we're off the record. 19 (Whereupon, a luncheon recess was 20 taken.) 21 22 23 24</p>
<p style="text-align: center;">Page 147</p> <p>1 Q. Three items down from there, "Audit 2 carrier records annually." Your name is listed. 3 Is that something that you participated in? 4 A. At that time, yes. 5 Q. Do you recall an individual named John 6 Gillies? 7 A. Yes. 8 Q. What was his role? 9 A. He was not here at the time. This 10 was -- Bill Ratliff was the security director. 11 John Gillies is the vice president of global 12 security. 13 Q. Currently? 14 A. Yes. John Gillies was Bill Ratliff's 15 successor. 16 Q. Okay. So to the extent Mr. Ratliff is 17 identified as having responsibilities on this 18 risk map action plan, currently those would be 19 Mr. Gillies responsibilities? 20 MR. O'CONNOR: Objection to form. 21 BY MR. GOTTO: 22 Q. As far as you know. 23 A. Yes. We don't have this product 24 anymore.</p>	<p style="text-align: center;">Page 149</p> <p>1 AFTERNOON SESSION 2 3 THE VIDEOGRAPHER: The time is 4 1:15 p.m., and we're on the record. 5 BY MR. GOTTO: 6 Q. Welcome back, Ms. Spaulding. 7 A. Thank you. 8 Q. Before our lunch break you had 9 testified about the one suspicious order you 10 could recall, which I think was a fentanyl order 11 that went to a vet clinic, is that correct? 12 A. Yes. 13 Q. Okay. You'd agree with me that if a 14 vet clinic purchased opioids and then resold 15 them to a human pain clinic or a human 16 physician, that would be a potentially 17 suspicious order, wouldn't it? 18 MR. O'CONNOR: Objection to form. 19 A. I wouldn't know if a vet clinic sold 20 it to anybody else. We would only have the 21 direct sales. And a vet clinic wouldn't apply 22 with chargebacks. 23 BY MR. GOTTO: 24 Q. So you're not aware of any situations</p>

Page 150	Page 152
<p>1 in which Mallinckrodt opioids were purchased by 2 a veterinary supply company and then resold to 3 medical clinics or dispensing physicians?</p> <p>4 A. Not that I'm aware of.</p> <p>5 Q. And do you know if Mallinckrodt's 6 records would include that information if it 7 had, in fact, occurred?</p> <p>8 A. I don't know what our records -- that 9 our records would include that.</p> <p>10 Q. In any event, you've never heard of 11 that happening?</p> <p>12 A. Correct.</p> <p>13 (Whereupon, Mallinckrodt-Spaulding-8 14 was marked for identification.)</p> <p>15 BY MR. GOTTO:</p> <p>16 Q. Just one last question on that one 17 before you turn to that document.</p> <p>18 If you were aware of that happening, 19 that a veterinary supply company purchasing from 20 Mallinckrodt had resold to a medical clinic or 21 dispensing physician, would you have 22 investigated that as a potentially suspicious 23 order?</p> <p>24 A. Yes, we would have raised that to the</p>	<p>1 marketplace as MS Contin is extremely abused and 2 they want to know when we are going to start 3 producing from this facility."</p> <p>4 Do you recall DEA making that inquiry 5 of you?</p> <p>6 A. No.</p> <p>7 Q. Okay. Do you recall being aware in 8 2005 that MS Contin was extremely abused?</p> <p>9 A. Only based on this e-mail.</p> <p>10 Q. Do you recall being aware in 2005 that 11 Oxycodone ER would also have the potential to be 12 abused?</p> <p>13 A. Only based on this e-mail.</p> <p>14 Q. And Mallinckrodt began manufacturing 15 Oxycodone IR shortly after this, isn't that 16 correct?</p> <p>17 A. We were manufacturing -- which 18 strength of IR?</p> <p>19 Q. Well, in any strength.</p> <p>20 A. So we had been manufacturing oxycodone 21 5-milligram prior to this. I don't remember 22 when we started manufacturing oxycodone 23 15-milligram or 30-milligram IR.</p> <p>24 Q. Okay. And Oxycodone IR also has the</p>
<p style="text-align: center;">Page 151</p> <p>1 suspicious order monitoring team for evaluation.</p> <p>2 Q. Okay. I've just handed you what we've 3 marked as Exhibit 8, which is a single-page 4 document bearing Bates MNK-T1_0006443249, an 5 e-mail thread from 2005. Take a look at that 6 for a moment, if you would, and tell me if you 7 recognize it.</p> <p>8 A. Okay.</p> <p>9 Q. Do you recall those e-mails?</p> <p>10 A. No.</p> <p>11 Q. Okay. Do you know who Mike Spears 12 was?</p> <p>13 A. Yes.</p> <p>14 Q. Who was he?</p> <p>15 A. Director of what we call PPT, product 16 process technology.</p> <p>17 Q. And how about Laura Ashline?</p> <p>18 A. She's a project manager.</p> <p>19 Q. Okay. And Jim Walter?</p> <p>20 A. He was the site director.</p> <p>21 Q. Okay. Your e-mail to Mr. Spears and 22 Ms. Ashline says "At the request of the DEA they 23 would like to know the timeline for release of 24 Oxycodone ER products (all strengths) into the</p>	<p style="text-align: center;">Page 153</p> <p>1 potential for abuse, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And were you aware of that back in 4 2005?</p> <p>5 A. I don't remember when I was aware of 6 it.</p> <p>7 Q. Okay. All right. You can set that 8 aside.</p> <p>9 (Whereupon, Mallinckrodt-Spaulding-9 10 was marked for identification.)</p> <p>11 BY MR. GOTTO:</p> <p>12 Q. We've marked as Exhibit 9 a two-page 13 e-mail thread beginning at Bates 14 MNK-T1_0000492214. Take a look at those 15 e-mails, if you would, and tell me if you 16 recognize them.</p> <p>17 (Witness reviewing document.)</p> <p>18 A. Yes.</p> <p>19 Q. And do you recognize these as e-mails 20 from April of 2007 involving you and Ms. Harper 21 as well as some others concerning a suspension 22 of AmerisourceBergen by FDA -- by DEA?</p> <p>23 A. Yes.</p> <p>24 Q. Do you recall that circumstance</p>

Page 154	Page 156
<p>1 occurring?</p> <p>2 A. Yes.</p> <p>3 Q. And AmerisourceBergen was a large</p> <p>4 customer of Mallinckrodt, correct?</p> <p>5 A. Yes.</p> <p>6 Q. And they, according to this press</p> <p>7 report, they were temporarily suspended as a</p> <p>8 result of shipping to certain pharmacies in</p> <p>9 Florida, correct?</p> <p>10 A. Based on this release, yes.</p> <p>11 Q. And this is dated in 2007. Were there</p> <p>12 any steps taken in 2007 in light of this</p> <p>13 suspension of AmerisourceBergen to evaluate</p> <p>14 whether any AmerisourceBergen orders from</p> <p>15 Mallinckrodt were suspicious?</p> <p>16 A. I don't remember if there was any</p> <p>17 specific steps.</p> <p>18 Q. Was there an audit conducted of</p> <p>19 AmerisourceBergen?</p> <p>20 MR. O'CONNOR: Objection to form.</p> <p>21 A. Not that I was directly involved in.</p> <p>22 BY MR. GOTTO:</p> <p>23 Q. Were you aware of an audit being</p> <p>24 conducted of AmerisourceBergen at any time in</p>	<p>1 A. Yes.</p> <p>2 Q. And did you ever hear anyone express</p> <p>3 that attitude?</p> <p>4 A. There was internal pushback both ways,</p> <p>5 so they would push back on us and we would push</p> <p>6 back as well.</p> <p>7 Q. And when you say "they" in that</p> <p>8 setting, who is the they?</p> <p>9 A. Management, stakeholders in the</p> <p>10 business.</p> <p>11 Q. And pushback on whom?</p> <p>12 A. The compliance team.</p> <p>13 Q. And what would the form of the</p> <p>14 pushback be?</p> <p>15 A. If we wanted to purchase physical --</p> <p>16 additional equipment for physical security to</p> <p>17 make us -- to enhance, but at all times it</p> <p>18 was -- we were always in compliance. It was</p> <p>19 always to make us better or to be able to look</p> <p>20 at things differently. At no time were we not</p> <p>21 compliant. If we were, we -- the business would</p> <p>22 have given us anything we needed to be</p> <p>23 compliant.</p> <p>24 Q. So one form of pushback that you're</p>
<p>1 the 2007 time frame?</p> <p>2 A. No, not that I can recall.</p> <p>3 Q. Or in 2008?</p> <p>4 A. No.</p> <p>5 Q. Or 2009?</p> <p>6 A. No.</p> <p>7 Q. Or 2010?</p> <p>8 A. No.</p> <p>9 Q. Now, in your e-mail, the second one on</p> <p>10 the first page of the exhibit, you note that</p> <p>11 AmerisourceBergen had already been reinstated by</p> <p>12 the DEA. How did you know that?</p> <p>13 A. I don't remember how I knew back at</p> <p>14 that time.</p> <p>15 Q. And Ms. Harper in her April 27th</p> <p>16 e-mail says "sometimes we are met with internal</p> <p>17 pushback and the attitude that we are 'such big</p> <p>18 players' that DEA would never suspend our</p> <p>19 license."</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. Do you recall Ms. Harper expressing</p> <p>23 that sentiment to you, that sometimes that that</p> <p>24 attitude was expressed at Mallinckrodt?</p>	<p>1 recalling is where you may have made a request</p> <p>2 for some sort of enhancement to security and</p> <p>3 that request was rejected?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. Was challenged.</p> <p>6 BY MR. GOTTO:</p> <p>7 Q. Do you remember any specific request</p> <p>8 in that regard?</p> <p>9 A. Nothing specific.</p> <p>10 Q. So the attitude that Ms. Harper is</p> <p>11 referring to is one that "we are 'such big</p> <p>12 players' that DEA would never suspend our</p> <p>13 license." If you were in compliance with DEA</p> <p>14 regulation and you were requesting an</p> <p>15 enhancement, how would that trigger a response</p> <p>16 in the nature of "we are 'such big players' that</p> <p>17 DEA would never suspend our license"?</p> <p>18 MR. O'CONNOR: Objection to form.</p> <p>19 A. I don't know what example that Karen</p> <p>20 is referring to in this -- in her comment.</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. You don't recall any discussions with</p> <p>23 her on that point in this time frame?</p> <p>24 A. No.</p>

Page 158	Page 160
<p>1 Q. Did Ms. Harper ever express to you any 2 frustration with the slow pace of enhancing the 3 SOM program?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. Not that I can recall.</p> <p>6 BY MR. GOTTO:</p> <p>7 Q. It took quite a while from when you 8 began working on enhancing the program until 9 there actually was an enhanced program in place, 10 wasn't it?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. I don't know what that time frame is. 13 I don't know what a while is.</p> <p>14 BY MR. GOTTO:</p> <p>15 Q. More than three years?</p> <p>16 A. I don't know, because they were 17 working on it from the corporate aspect.</p> <p>18 Q. In terms of when you were first aware 19 of there being work on enhancing the SOM program 20 until the time when the enhanced program was 21 actually implemented, that was more than three 22 years, wasn't it?</p> <p>23 MR. O'CONNOR: Objection to form.</p> <p>24 A. I don't remember. We were constantly</p>	<p>1 Q. In your e-mail on June 24th, you 2 indicate "Patti is sharing with her group as 3 well."</p> <p>4 Who is Patti?</p> <p>5 A. Patti Woznick was the purchasing 6 manager.</p> <p>7 Q. Okay. And what was her group?</p> <p>8 A. The purchasing department, and the 9 ARCos coordinator at the time was reporting to 10 Patti.</p> <p>11 Q. Okay. And Ms. Harper was forwarding 12 you some press reports regarding oxycodone and 13 OxyContin, correct?</p> <p>14 A. Yes.</p> <p>15 Q. And what would be the reason for Patti 16 sharing that information with her group?</p> <p>17 A. Because she had a member of compliance 18 on her team.</p> <p>19 Q. Fair to say that by mid 2008 you were 20 aware of the potential for diversion and abuse 21 of oxycodone, correct?</p> <p>22 A. Yes. Yes.</p> <p>23 Q. And fair to say it was a matter of 24 concern for Ms. Harper at that time?</p>
<p style="text-align: center;">Page 159</p> <p>1 working on it. There was always a program in 2 place, we were just always tweaking it, making 3 it better.</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. Were you personally frustrated with 6 the pace at which the enhancement of the SOM 7 program was taking place?</p> <p>8 A. No, not that I can recall.</p> <p>9 Q. And you don't recall Ms. Harper 10 expressing any frustration in that regard?</p> <p>11 A. No, not to me.</p> <p>12 (Whereupon, Mallinckrodt-Spaulding-10 13 was marked for identification.)</p> <p>14 BY MR. GOTTO:</p> <p>15 Q. We've marked as Exhibit 10 a 16 multi-page e-mail thread beginning at Bates 17 MNK-T1_0001792949. Please take a moment to look 18 at those e-mails, and tell me if you recognize 19 them.</p> <p>20 (Witness reviewing document.)</p> <p>21 Q. I just have questions for you on the 22 first page.</p> <p>23 (Witness reviewing document.)</p> <p>24 A. Okay.</p>	<p style="text-align: center;">Page 161</p> <p>1 MR. O'CONNOR: Objection to form.</p> <p>2 A. I can't speculate on what Karen felt 3 or knew.</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. You don't recall her expressing to you 6 at that time any concerns about the potential 7 for diversion or abuse of oxycodone?</p> <p>8 MR. O'CONNOR: Objection to form.</p> <p>9 A. Not at this time.</p> <p>10 BY MR. GOTTO:</p> <p>11 Q. When can you recall her first 12 expressing any such concerns to you?</p> <p>13 MR. O'CONNOR: Objection to form.</p> <p>14 A. I don't remember exact dates or 15 timelines.</p> <p>16 BY MR. GOTTO:</p> <p>17 Q. You understood in 2008, didn't you, 18 that as a DEA registrant Mallinckrodt had an 19 obligation to design and implement a suspicious 20 order monitoring program, correct?</p> <p>21 A. Yes.</p> <p>22 Q. And you understood that a purpose of 23 that program was to function as an 24 anti-diversion mechanism, correct?</p>

Page 162	Page 164
<p>1 MR. O'CONNOR: Objection to form.</p> <p>2 A. I understood it to be a regulation in</p> <p>3 the CFR.</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. Did you understand one of the purposes</p> <p>6 for suspicious order monitoring to deter</p> <p>7 diversion?</p> <p>8 A. Yes.</p> <p>9 Q. And you understood in 2008 that as a</p> <p>10 DEA registrant Mallinckrodt also had the</p> <p>11 obligation to take steps to protect against</p> <p>12 diversion of the controlled substances that it</p> <p>13 manufactured?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. We had to maintain effective controls</p> <p>16 to detect diversion within the manufacturing</p> <p>17 site.</p> <p>18 BY MR. GOTTO:</p> <p>19 Q. Did you have an understanding as to</p> <p>20 whether Mallinckrodt had any duties with respect</p> <p>21 to controlling against diversion with respect to</p> <p>22 its products after they left the manufacturing</p> <p>23 site?</p> <p>24 A. No.</p>	<p>1 something that somebody else saw on the SOM team</p> <p>2 or it was broader.</p> <p>3 Q. Was the subject of conducting inquiry</p> <p>4 into your customers' customers something that</p> <p>5 was covered in any of the DEA-sponsored</p> <p>6 educational programs that you attended?</p> <p>7 A. I vaguely remember one of the DEA</p> <p>8 conferences talking about know your customer's</p> <p>9 customer, but I don't know when that was.</p> <p>10 Q. Do you recall if at that time</p> <p>11 Mallinckrodt was taking steps to know its</p> <p>12 customer's customer?</p> <p>13 A. No, because I don't remember what the</p> <p>14 correlation time was.</p> <p>15 Q. How about the Buzzeo conferences, do</p> <p>16 you recall that topic, knowing your customer's</p> <p>17 customer, being covered at any of those</p> <p>18 conferences?</p> <p>19 A. No.</p> <p>20 Q. Do you recall that in 2008 there was</p> <p>21 an initiative at Mallinckrodt to enhance the SOM</p> <p>22 program?</p> <p>23 A. Yes.</p> <p>24 Q. And do you recall what triggered that?</p>
<p style="text-align: center;">Page 163</p> <p>1 Q. Did you not have an understanding, or</p> <p>2 did you understand that it did not have any such</p> <p>3 obligation?</p> <p>4 A. So my understanding was that we had an</p> <p>5 obligation to maintain effective controls from</p> <p>6 us to the customer, to our direct customer.</p> <p>7 Back in 2008 we didn't know about downstream</p> <p>8 customers, or have the inclination that we</p> <p>9 needed to be looking at downstream customers.</p> <p>10 Q. Okay. And when you say "downstream</p> <p>11 customers," you mean your customers' customers,</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. And when did you first -- when can you</p> <p>15 recall first beginning to conduct any inquiry</p> <p>16 into Mallinckrodt's customers' customers?</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. That would have been when we started</p> <p>19 looking at chargebacks.</p> <p>20 BY MR. GOTTO:</p> <p>21 Q. And do you recall when that was?</p> <p>22 A. I don't.</p> <p>23 Q. Do you recall what triggered that?</p> <p>24 A. I don't. I don't know if it was</p>	<p style="text-align: center;">Page 165</p> <p>1 A. No.</p> <p>2 Q. How did you learn about that</p> <p>3 initiative?</p> <p>4 A. The initiative of --</p> <p>5 Q. Enhancing the SOM program.</p> <p>6 A. Through Karen Harper.</p> <p>7 Q. And was one of the reasons for that</p> <p>8 initiative increased DEA scrutiny with respect</p> <p>9 to Mallinckrodt's distributors?</p> <p>10 A. I don't know that firsthand.</p> <p>11 Q. Was one of the reasons any of the</p> <p>12 letters from Mr. Rannazzisi that you mentioned</p> <p>13 earlier today?</p> <p>14 A. It could be.</p> <p>15 Q. But you don't recall?</p> <p>16 A. I don't recall exactly, no.</p> <p>17 Q. Do you recall in 2008 being aware that</p> <p>18 diversion of prescription opioids was being</p> <p>19 identified publicly as a significant health</p> <p>20 issue?</p> <p>21 MR. O'CONNOR: Objection to form.</p> <p>22 A. I'm aware of it. I don't remember</p> <p>23 when I became aware of it.</p> <p>24 (Whereupon, Mallinckrodt-Spaulding-11</p>

Page 166	Page 168
<p>1 was marked for identification.)</p> <p>2 BY MR. GOTTO:</p> <p>3 Q. We've marked as Exhibit 11 a two-page</p> <p>4 DEA letter beginning at Bates MNK-T1_0000270069.</p> <p>5 Take a look at that, and tell me if you</p> <p>6 recognize that as one of the letters from</p> <p>7 Mr. Rannazzisi that you testified about earlier</p> <p>8 today.</p> <p>9 A. Yes.</p> <p>10 Q. Do you recall seeing this letter in</p> <p>11 late 2007 or early 2008?</p> <p>12 A. I recall seeing it. I would assume it</p> <p>13 was when this letter was sent. I don't remember</p> <p>14 exactly.</p> <p>15 Q. And do you recall who provided it to</p> <p>16 you?</p> <p>17 A. So based on the stamp, this came into</p> <p>18 our regulatory affairs department, and they</p> <p>19 probably shared it with me.</p> <p>20 Q. Okay. Do you recall when you first</p> <p>21 saw this letter if this provided any information</p> <p>22 with respect to DEA regulation of which you were</p> <p>23 not aware until you read the letter?</p> <p>24 MR. O'CONNOR: Objection to form.</p>	<p>1 about halfway through there's a sentence that</p> <p>2 says "The regulation clearly indicates that it</p> <p>3 is the sole responsibility of the registrant to</p> <p>4 design and operate such a system."</p> <p>5 Do you see that in that system to</p> <p>6 disclose suspicious orders?</p> <p>7 A. Yes.</p> <p>8 Q. You were aware of that before you</p> <p>9 received the letter, correct?</p> <p>10 A. Yes.</p> <p>11 Q. In the following paragraph, the second</p> <p>12 sentence says "Filing a monthly report of</p> <p>13 completed transactions does not meet the</p> <p>14 regulatory requirement to report suspicious</p> <p>15 orders."</p> <p>16 Were you aware of that before you</p> <p>17 received this letter?</p> <p>18 MR. O'CONNOR: Objection to form.</p> <p>19 A. I'm not following where you are in the</p> <p>20 letter.</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. I'm sorry. The third paragraph,</p> <p>23 second sentence, "Filing a monthly report."</p> <p>24 A. Okay.</p>
<p style="text-align: center;">Page 167</p> <p>1 A. I remember that the letter called out</p> <p>2 that they didn't want excessive order reports</p> <p>3 anymore. They only wanted orders that were</p> <p>4 suspicious.</p> <p>5 BY MR. GOTTO:</p> <p>6 Q. Okay. And excessive order reports</p> <p>7 were something that you had provided previously,</p> <p>8 correct?</p> <p>9 A. Yes.</p> <p>10 Q. And did you stop doing that after</p> <p>11 receiving this letter?</p> <p>12 A. I stopped doing it. I don't know that</p> <p>13 it was a result of receiving this letter or</p> <p>14 when.</p> <p>15 Q. The second paragraph of the letter in</p> <p>16 the second line notes that manufacturers and</p> <p>17 distributors must maintain effective controls</p> <p>18 against diversion.</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. You were aware of that before you</p> <p>22 received this letter, correct?</p> <p>23 A. Yes.</p> <p>24 Q. A little later in that paragraph,</p>	<p style="text-align: center;">Page 169</p> <p>1 Q. Were you aware of what that sentence</p> <p>2 said before you received this letter?</p> <p>3 MR. O'CONNOR: Same objection.</p> <p>4 A. I don't remember.</p> <p>5 BY MR. GOTTO:</p> <p>6 Q. Two sentences later in that paragraph</p> <p>7 it says "Registrants must conduct an independent</p> <p>8 analysis of suspicious orders prior to</p> <p>9 completing a sale to determine whether the</p> <p>10 controlled substances are likely to be diverted</p> <p>11 from legitimate channels."</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Were you aware of that before</p> <p>15 receiving this letter?</p> <p>16 A. I don't remember.</p> <p>17 Q. But in any event, you were aware of it</p> <p>18 after you read this letter, correct?</p> <p>19 A. Yes.</p> <p>20 Q. Was it your understanding in late</p> <p>21 2007, early 2008 that Mallinckrodt's procedures</p> <p>22 complied with that requirement, namely to</p> <p>23 conduct an independent analysis of suspicious</p> <p>24 orders before completing a sale to determine</p>

Page 170	Page 172
1 whether the controlled substances were likely to 2 be diverted from legitimate channels?	1 Mallinckrodt's SOM program -- well, do you know 2 if at the time of this letter the description 3 that I just read from this letter would apply to 4 Mallinckrodt's SOM program as it was followed in 5 this time frame?
3 MR. O'CONNOR: Objection.	6 MR. O'CONNOR: Objection to form.
4 A. Yes.	7 A. I don't know what the algorithm in 8 place was at the time of this letter.
5 BY MR. GOTTO:	9 BY MR. GOTTO:
6 Q. What did that independent analysis 7 consist of in this time frame?	10 Q. Okay. You can set that aside. 11 (Whereupon, Mallinckrodt-Spaulding-12 12 was marked for identification.)
8 A. I don't remember exactly. It was 9 being done at corporate.	13 BY MR. GOTTO:
10 Q. It's not something you were involved 11 in at this time?	14 Q. We've marked as Exhibit 11 a one-page 15 document MNK-T1_0000496062, Suspicious Order 16 Monitoring Team Charter.
12 A. I don't think so. I don't remember.	17 MR. O'CONNOR: Counsel, I think it's 18 12.
13 Q. Do you know who at corporate was 14 involved in that?	19 MR. GOTTO: I'm sorry. Is it 12?
15 A. Customer service managers.	20 MS. REYES: It is 12.
16 Q. The next paragraph says "The 17 regulation specifically states that suspicious 18 orders include orders of an unusual size, orders 19 deviating substantially from a normal pattern, 20 and orders of unusual frequency."	21 MR. GOTTO: Sorry. I apologize.
21 Do you see that?	22 Exhibit 12.
22 A. Yes.	23 MR. O'CONNOR: No problem.
23 Q. Were you aware of that before you 24 received this letter?	24 BY MR. GOTTO:
Page 171	Page 173
1 A. Yes.	1 Q. Updated 4/7/11. Take a look at that
2 Q. On the second page, the first	2 document, if you would, tell me if you recognize
3 paragraph on that page says "Registrants that	3 it.
4 rely on rigid formulas to" determine "whether an	4 (Witness reviewing document.)
5 order is suspicious may be failing to detect	5 A. Okay.
6 suspicious orders."	6 Q. Do you recognize that document?
7 Do you see that?	7 A. No, I don't remember it.
8 A. Yes.	8 Q. Appears to be a team charter for the
9 Q. Were you aware of that before	9 SOM team. You're listed on -- as a member of
10 receiving this letter?	10 the steering committee.
11 A. I don't remember.	11 Do you see that?
12 Q. The following sentence says "For	12 A. Yes.
13 example, a system that identifies orders as	13 Q. And is that consistent with your
14 suspicious only if the total amount of the	14 recollection that you were a member of the SOM
15 controlled substance ordered during one month	15 steering committee at least as of April 7 of
16 exceeds the amount ordered the previous month by	16 2011?
17 a certain percentage or more is insufficient."	17 A. Yes.
18 Do you see that?	18 Q. Do you recall when you became a member
19 A. Yes.	19 of the steering committee?
20 Q. Were you aware before receiving this	20 A. No.
21 letter that a system of the type described in	21 Q. When you were a member, do you
22 that sentence is insufficient?	22 recall -- are you still a member of the steering
23 A. I don't remember.	23 committee?
24 Q. Do you know if at this time	24 A. Yes.

Page 174	Page 176
<p>1 Q. And does the steering committee meet 2 regularly?</p> <p>3 A. Yes.</p> <p>4 Q. How frequently?</p> <p>5 A. Monthly.</p> <p>6 Q. Has that been the case at least since 7 April of 2011?</p> <p>8 A. Yes.</p> <p>9 Q. Does it maintain minutes of meetings?</p> <p>10 A. Not that I'm aware of.</p> <p>11 Q. Any other formal documentation of its 12 actions or deliberations?</p> <p>13 A. No.</p> <p>14 (Whereupon, Mallinckrodt-Spaulding-13 15 was marked for identification.)</p> <p>16 BY MR. GOTTO:</p> <p>17 Q. We've marked as Exhibit 13 a two-page 18 document starting MNK-T1_0007026341. Please 19 take a look at those pages, and tell me if you 20 recognize them.</p> <p>21 (Witness reviewing document.)</p> <p>22 A. Yes.</p> <p>23 Q. And what are they?</p> <p>24 A. So this is actually -- I know the</p>	<p>1 Q. Okay. Do you recall why you sent this 2 report to Ms. Harper in 2014?</p> <p>3 A. She would have had to have requested 4 it is the only reason I would have sent it.</p> <p>5 Q. Now, in your cover e-mail you mention 6 a suspicious order monitoring of some type from 7 2001. Was there a written suspicious order 8 monitoring program in place before 2008?</p> <p>9 MR. O'CONNOR: Object to form.</p> <p>10 A. I don't know that it was written, that 11 there was a written policy on it.</p> <p>12 BY MR. GOTTO:</p> <p>13 Q. Okay. So you don't recall seeing a 14 written policy prior to 2008?</p> <p>15 A. No.</p> <p>16 Q. How did you come to know what the 17 program was if it wasn't written?</p> <p>18 A. Because Elizabeth McPhail at the time 19 would have trained me on what to look for in the 20 orders.</p> <p>21 Q. And what do you recall her training 22 you on in that regard?</p> <p>23 A. To look at the orders that come out, 24 and if they were of concern to research them</p>
Page 175	Page 177
<p>1 header says suspicious orders, but these are 2 what we call as peculiar or unusual orders, so 3 they're hits to the algorithm.</p> <p>4 Q. Okay. Your cover e-mail, which is 5 dated in April of 2014 to Ms. Harper, says "I 6 can recall having a suspicious order monitoring 7 system in place of some type with the start of 8 distribution activities from Hobart 2001, 9 however the attached is the earliest SOM report 10 that I have in my e-mail system." And the 11 attachment is from December of 2003, correct?</p> <p>12 A. Yes.</p> <p>13 Q. And this identifies four transactions. 14 And I take it from your earlier answer these 15 were identified as peculiar, correct?</p> <p>16 A. Yes.</p> <p>17 Q. And is it the case that none of these 18 were ultimately determined to be suspicious?</p> <p>19 A. Correct.</p> <p>20 Q. And I think you've testified earlier 21 the only order that you can recall being 22 identified as suspicious was the fentanyl order 23 to the vet clinic, correct?</p> <p>24 A. The only one I know of, yes.</p>	<p>1 further.</p> <p>2 Q. And did she train you as to what 3 characteristics of an order might raise concern?</p> <p>4 A. No, because we really didn't have a 5 whole lot of information of what was unusual.</p> <p>6 Q. And so, for example, the orders 7 identified as peculiar in the attachment to 8 Exhibit 13, do you recall how you identified 9 those orders as peculiar?</p> <p>10 A. So the system would have ran these 11 orders against whatever algorithm was in place 12 at that time, and then these orders, these 13 orders went on hold. So the report is saying 14 their previous year-to-date average is 643, and 15 this order was for 1,380.</p> <p>16 Q. Okay. So these orders were identified 17 by application of the algorithm that you 18 understand was in place at the time?</p> <p>19 A. Yes.</p> <p>20 Q. But you don't know what the components 21 of that algorithm were, correct?</p> <p>22 A. All I know, it was based on previous 23 history. I don't know the specifics.</p> <p>24 Q. Okay. You can set that aside.</p>

Page 178	Page 180
<p>1 (Whereupon, Mallinckrodt-Spaulding-14 2 was marked for identification.)</p> <p>3 BY MR. GOTTO:</p> <p>4 Q. We've marked as Exhibit 14 a 5 single-page document, MNK-T1_0004282621. It's a 6 2007 e-mail from you to Sarah Heideman.</p> <p>7 First of all, who was Sarah Heideman?</p> <p>8 A. I don't remember.</p> <p>9 Q. Okay.</p> <p>10 A. I don't know.</p> <p>11 Q. In the body of your e-mail -- first of 12 all, no reason to doubt you sent this e-mail, 13 correct?</p> <p>14 A. No.</p> <p>15 Q. The body of your e-mail, you say "DEA 16 requires us to report any 'suspicious orders'. 17 IS programmed a report that takes last year's 18 average YTD and comes up with a formula and 19 anything outside of that formula shows on this 20 report."</p> <p>21 Is that the algorithm that you're 22 referring to?</p> <p>23 A. Yes.</p> <p>24 Q. And you have -- you ask Ms. Heideman</p>	<p>1 order, is that what you're saying in this 2 sentence?</p> <p>3 A. YTD is year-to-date, so the formula at 4 that time was taking the last year's 5 year-to-date average, and this order was double 6 their last year year-to-date average.</p> <p>7 Q. And so would this -- is this e-mail an 8 example of your looking at an order that had 9 been identified as peculiar to determine whether 10 it was suspicious?</p> <p>11 A. At this time, yes.</p> <p>12 Q. And you did that by providing this 13 information to Ms. Heideman and asking her for 14 some feedback on it?</p> <p>15 A. Yes.</p> <p>16 Q. And do you recall if you ultimately 17 concluded whether this order was suspicious or 18 not?</p> <p>19 A. It wasn't reported to DEA, that I'm 20 aware of.</p> <p>21 Q. Okay.</p> <p>22 (Whereupon, Mallinckrodt-Spaulding-15 23 was marked for identification.)</p> <p>24 BY MR. GOTTO:</p>
<p style="text-align: center;">Page 179</p> <p>1 to take a look and let you know what she thinks.</p> <p>2 But you don't recall who Ms. Heideman 3 was or why you sent her this e-mail?</p> <p>4 A. Based on the context of this e-mail, 5 it leads me to believe Sarah Heideman was the 6 project -- or the account manager for Walmart, 7 because I'm asking her specifically about 8 Walmart orders.</p> <p>9 Q. Okay. And you note in your e-mail, 10 "It appears to me that Walmart is ordering 11 double what was last years' YTD amount, more 12 than the 20 percent market share increase."</p> <p>13 Your reference there to market share, 14 what are you referring to?</p> <p>15 A. So we would have received information 16 from the marketing group as to which customers 17 have -- which have how much of the market share. 18 So at this time I must have been advised by 19 somebody in marketing that Walmart had 20 20 percent market share.</p> <p>21 Q. Or 20 percent market share increase?</p> <p>22 A. Yeah. Yes.</p> <p>23 Q. Okay. So you're comparing that 24 increase to the increase in the size of their</p>	<p style="text-align: center;">Page 181</p> <p>1 Q. We've marked as Exhibit 15 a two-page 2 document beginning at MNK-T1_0000274399, an 3 e-mail exchange involving you and Ms. Harper, 4 "Re: Controlled Substance Suspicious Order 5 Monitoring Team Update." Take a look at those 6 e-mails, and tell me if you recognize them.</p> <p>7 (Witness reviewing document.)</p> <p>8 A. Okay.</p> <p>9 Q. Okay. Do you recognize those e-mails?</p> <p>10 A. No, I don't remember them 11 specifically.</p> <p>12 Q. Okay. The second e-mail on the page 13 from you to Ms. Harper dated June 17, do you see 14 that?</p> <p>15 A. Yes.</p> <p>16 Q. Any reason to doubt you sent that 17 e-mail?</p> <p>18 A. No.</p> <p>19 Q. Okay. You say to Ms. Harper, the 20 first paragraph suggests on the customer 21 checklist, "fill in what type of DEA 22 registration so that we may be able to identify 23 if a customer is ordering a suspicious amount 24 against a specific registration type."</p>

Page 182	Page 184
1 What did you mean by that?	1 A. I don't know what he provided.
2 A. So if a customer that's listed as a	2 (Whereupon, Mallinckrodt-Spaulding-16
3 researcher is ordering a huge amount of product,	3 was marked for identification.)
4 that would not be normal for a researcher	4 BY MR. GOTTO:
5 license.	5 Q. We've marked as Exhibit 16 a two-page
6 Q. Okay. And the customer checklist that	6 document beginning at Bates MNK-T1_0002940798.
7 you're referring to here, what was that?	7 Please take a look at those and tell me if you
8 A. To the best that I recall, there	8 can identify them.
9 was -- the SOM corporate team was developing	9 (Witness reviewing documents.)
10 checklists to be sent out to our customers.	10 A. Okay.
11 Q. Was this part of the enhancement of	11 Q. Do you recognize those documents?
12 the SOM?	12 A. Yes.
13 A. Yes.	13 Q. What are they?
14 Q. The last paragraph of your June 17th,	14 A. These were the quarterly reports that
15 or the last substantive paragraph says "With the	15 I was combining and sending to DEA.
16 new procedures, what kind of report will I send	16 Q. Okay. And these were -- what is
17 to the DEA? I realize that we will DEA report	17 reported on the report?
18 any order that is deemed suspicious by yours and	18 A. I'm not sure I understand your
19 Bill's group, but what if we go a quarter	19 question.
20 without a suspicious order?"	20 Q. I'm sorry. How does some -- how does
21 Do you see that?	21 an order -- what is it about an order that
22 A. Yes.	22 causes you to include it on this report?
23 Q. So was your -- does that indicate that	23 A. So if it hits the criteria for the
24 up until this time there was a regular quarterly	24 algorithm.
Page 183	Page 185
1 report you were sending to the DEA?	1 Q. Okay. So these would be, again,
2 A. It was the excessive orders report.	2 peculiar orders under the Mallinckrodt
3 Q. Okay. And so does that paragraph	3 terminology?
4 indicate that you were not going to be providing	4 A. Yes.
5 that report to the DEA anymore? Correct?	5 Q. Okay. And so did you report all
6 A. Correct.	6 peculiar orders on a quarterly basis to the DEA
7 Q. And so what was the answer to the	7 for some period of time?
8 question that you posed in that paragraph?	8 A. We reported all orders that -- these
9 A. I don't remember.	9 are all clinic orders.
10 Q. You can set that aside.	10 Q. Clinic orders that had been identified
11 Do you know who Bill Rausch was?	11 as peculiar?
12 A. Bill Rausch --	12 A. Yes.
13 Q. Rausch.	13 Q. As compared to what other types of
14 A. -- or Jim Rausch?	14 orders?
15 Q. Jim Rausch, I'm sorry.	15 A. So the distributors have been removed.
16 A. Jim Rausch, yes.	16 Q. Okay. And what was the reason for
17 Q. Who was he?	17 that?
18 A. He was a customer service manager.	18 A. I don't remember specifically. I
19 Q. Did he have any involvement at any	19 remember being told not to include the
20 time that you can recall in the SOM process?	20 distributors into the report, but I don't
21 A. Yes, he was the customer service	21 remember who told me not to include the
22 manager reviewing the peculiar order report.	22 distributors.
23 Q. Okay. And did he provide reports to	23 Q. Would it have been someone other than
24 the DEA from time to time that you know of?	24 Ms. Harper?

Page 186	Page 188
<p>1 A. It could have been.</p> <p>2 Q. Okay. And you don't remember -- you</p> <p>3 weren't given a reason for that, I take it?</p> <p>4 A. I know that I was told not to include</p> <p>5 them, but I can't remember by whom. It could</p> <p>6 have been any number of people.</p> <p>7 Q. So in Exhibit 15, that was an e-mail</p> <p>8 in 2008 in which you posed the question about</p> <p>9 what kind of report will you be sending to the</p> <p>10 DEA going forward.</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. In 2010, judging from Exhibit 16, in</p> <p>14 2010 you were still providing some sort of</p> <p>15 quarterly report to the DEA, correct?</p> <p>16 A. Yes. Well, this was -- the last</p> <p>17 report was 2008. My e-mail to Karen was 2010,</p> <p>18 but the last report was 2008.</p> <p>19 Q. Okay. So your 2010 e-mail is</p> <p>20 attaching a 2008 report?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. So the attachment to Exhibit 16</p> <p>23 is the final report that you sent to the DEA,</p> <p>24 the final quarterly report?</p>	<p>1 A. Roughly, yes.</p> <p>2 Q. Okay. And do you continue -- is that</p> <p>3 procedure still in place?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. So from the attachment to</p> <p>6 Exhibit 16, after that report and prior to the</p> <p>7 time when you in 2012 began the twice daily</p> <p>8 unusual order report to the DEA, was there any</p> <p>9 other reporting to the DEA other than if a</p> <p>10 report was -- if an order was determined to be</p> <p>11 suspicious?</p> <p>12 A. Not by me, but I don't know if DEA --</p> <p>13 or if corporate was sending anything to DEA.</p> <p>14 Q. Okay. But as far as reports that</p> <p>15 you're aware of, you're not aware of any during</p> <p>16 that time period?</p> <p>17 A. Correct. 2008 was the last of the</p> <p>18 quarterly excessive order reports. In 2012</p> <p>19 started the peculiar order reports.</p> <p>20 Q. Okay. You can set that aside.</p> <p>21 (Whereupon, Mallinckrodt-Spaulding-17</p> <p>22 was marked for identification.)</p> <p>23 BY MR. GOTTO:</p> <p>24 Q. We've marked as Exhibit 17 a</p>
Page 187	Page 189
<p>1 A. Yes.</p> <p>2 Q. Okay. And so after the report that's</p> <p>3 attached to Exhibit 16, what, if any, report did</p> <p>4 you provide to the DEA with respect to orders</p> <p>5 that were identified as peculiar but were not</p> <p>6 identified as suspicious?</p> <p>7 A. So what reports did we make to the DEA</p> <p>8 that were peculiar but not suspicious?</p> <p>9 Q. Yes.</p> <p>10 A. In what time frame?</p> <p>11 Q. Well, after the report that is</p> <p>12 attached to Exhibit 16.</p> <p>13 A. Right. We stopped this because this</p> <p>14 was basically the excessive order report, and</p> <p>15 the letter came out that said they didn't want</p> <p>16 the excessive order report, so that's why we</p> <p>17 discontinued sending them to DEA. And then we</p> <p>18 would have only reported suspicious orders.</p> <p>19 Q. Okay.</p> <p>20 A. In 2012, one of the iterations in the</p> <p>21 enhancements involved sending the peculiar order</p> <p>22 report, at this time we called it unusual order</p> <p>23 report, to DEA twice daily.</p> <p>24 Q. And that was in 2012?</p>	<p>1 multi-page e-mail thread, MNK-T1_0005663239 is</p> <p>2 the beginning. Take a moment to look at those.</p> <p>3 My questions are principally about</p> <p>4 your March 5, 2012 e-mail that begins the</p> <p>5 thread.</p> <p>6 (Witness reviewing document.)</p> <p>7 A. Okay.</p> <p>8 Q. Do you recognize those e-mails?</p> <p>9 A. I'm sorry?</p> <p>10 Q. Do you recognize those e-mails?</p> <p>11 A. No.</p> <p>12 Q. Okay. Turning to your March 5, 2012</p> <p>13 e-mail, which is on the third page, any reason</p> <p>14 to doubt you sent that e-mail?</p> <p>15 A. No.</p> <p>16 Q. Okay. So this is an e-mail that you</p> <p>17 send to a number of persons regarding an order</p> <p>18 from Quest Pharmaceuticals, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you indicate "I am unsure of the</p> <p>21 Product Manager for Hydrocodone and the NAM for</p> <p>22 Quest," correct?</p> <p>23 A. Yes.</p> <p>24 Q. And that's the reason you sent it to</p>

Page 190	Page 192
<p>1 all those parties, right?</p> <p>2 A. Correct.</p> <p>3 Q. Okay. Was there a -- well, strike</p> <p>4 that.</p> <p>5 So the order from Quest had been</p> <p>6 identified as a peculiar order, is that fair?</p> <p>7 A. Unusual, yes.</p> <p>8 Q. Peculiar or unusual?</p> <p>9 A. Yeah.</p> <p>10 Q. Meaning that it triggered the --</p> <p>11 whatever the algorithm was in place at the time,</p> <p>12 this triggered it?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And you indicate that the</p> <p>15 "items are double and in some cases triple the</p> <p>16 quantity previously ordered." Would your</p> <p>17 procedure at this time in 2012 have been to</p> <p>18 inquire of the product manager or the NAM to get</p> <p>19 further information with respect to an order</p> <p>20 that triggered the algorithm?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. And here you weren't sure who</p> <p>23 those individuals were, correct?</p> <p>24 A. Correct.</p>	<p>1 information.</p> <p>2 Q. Did you ever make inquiry of the</p> <p>3 customer service department to gain further</p> <p>4 information with respect to orders that had been</p> <p>5 identified as peculiar?</p> <p>6 A. Yes.</p> <p>7 Q. And who did you make inquiry of in the</p> <p>8 customer service department?</p> <p>9 A. It depends on the customer service rep</p> <p>10 assigned to the account.</p> <p>11 Q. Okay. So in this example on March 5th</p> <p>12 of 2012, are you making inquiry here of customer</p> <p>13 service?</p> <p>14 A. No.</p> <p>15 Q. And why not?</p> <p>16 A. Because customer service may not know</p> <p>17 why their order is higher. The product manager</p> <p>18 or the account manager may. I would inquire to</p> <p>19 customer service if I suspected that an order</p> <p>20 had been duplicated. There might have been an</p> <p>21 order entry error. But in this case, because of</p> <p>22 the order quantities, I went to the account</p> <p>23 manager who would know what the customer was</p> <p>24 ordering.</p>
<p style="text-align: center;">Page 191</p> <p>1 Q. Did you have any program in place to</p> <p>2 be made aware of who the project manager --</p> <p>3 product manager and NAMs were for particular</p> <p>4 products or customers?</p> <p>5 A. No.</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. Because they could change. So NAM is</p> <p>8 national account manager, and the product</p> <p>9 manager.</p> <p>10 BY MR. GOTTO:</p> <p>11 Q. Okay. And so when you had a peculiar</p> <p>12 or unusual order, was it your practice to</p> <p>13 inquire of both the product manager and the</p> <p>14 national account manager?</p> <p>15 A. Depends on the circumstances and the</p> <p>16 product.</p> <p>17 Q. Okay. Did you ever have any</p> <p>18 difficulty in receiving responses either from</p> <p>19 product managers or national account managers</p> <p>20 with respect to inquiries that you made</p> <p>21 regarding peculiar orders?</p> <p>22 A. Sometimes we'd have to send them a</p> <p>23 reminder e-mail if they were travelling that the</p> <p>24 order was still on hold and we were awaiting</p>	<p style="text-align: center;">Page 193</p> <p>1 Q. Okay. Do you know who Cathy Stewart</p> <p>2 was?</p> <p>3 A. Yes.</p> <p>4 Q. Who was she?</p> <p>5 A. She was a customer service manager.</p> <p>6 Q. Did you interact with her from time to</p> <p>7 time?</p> <p>8 A. Yes.</p> <p>9 Q. And she had customer service reps who</p> <p>10 reported to her, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And your March 5, 2012 e-mail, one of</p> <p>13 the persons that you address it to is Victor</p> <p>14 Borelli, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And did you deal with Mr. Borelli from</p> <p>17 time to time?</p> <p>18 A. Yes.</p> <p>19 Q. Did Ms. Stewart ever express to you,</p> <p>20 that you can recall, that one or more of the</p> <p>21 customer service reps who reported to her had</p> <p>22 expressed the view that Mr. Borelli would tell</p> <p>23 them anything to get a sale?</p> <p>24 MR. O'CONNOR: Objection to form.</p>

Page 194	Page 196
<p>1 A. Not that I remember.</p> <p>2 BY MR. GOTTO:</p> <p>3 Q. Okay. You can set that aside.</p> <p>4 (Whereupon, Mallinckrodt-Spaulding-18</p> <p>5 was marked for identification.)</p> <p>6 BY MR. GOTTO:</p> <p>7 Q. We've marked as Exhibit 18 a two-page</p> <p>8 e-mail thread beginning at Bates</p> <p>9 MNK-T1_0000280632. Take a moment to look at</p> <p>10 those e-mails, if you would.</p> <p>11 (Witness reviewing document.)</p> <p>12 A. Okay.</p> <p>13 Q. And do you recall this e-mail</p> <p>14 exchange?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. What do you recall of that?</p> <p>17 A. Karen was alerting me to some -- she</p> <p>18 had compiled a timeline and had sent me the</p> <p>19 timeline, and then was letting me know that all</p> <p>20 the orders had been reviewed by the customer</p> <p>21 service manager, and then later on in the e-mail</p> <p>22 she corrects terminology listed below.</p> <p>23 Q. Okay. In Ms. Harper's e-mail, she --</p> <p>24 the first e-mail, October 31, "In an effort to</p>	<p>1 Q. Okay. And in Ms. Harper's October 31</p> <p>2 e-mail, she says "during the last two years, all</p> <p>3 Peculiar Orders...were deemed to be okay and</p> <p>4 none rose to the level of Peculiar."</p> <p>5 Do you know if she meant there that</p> <p>6 none rose to the level of suspicious?</p> <p>7 MR. O'CONNOR: Objection.</p> <p>8 A. She did. In the earlier e-mail above</p> <p>9 she clarifies that --</p> <p>10 BY MR. GOTTO:</p> <p>11 Q. Okay.</p> <p>12 A. -- she meant none rose to the level of</p> <p>13 suspicious.</p> <p>14 Q. Okay. And that's consistent with your</p> <p>15 recollection you've already testified to in</p> <p>16 terms of orders being identified as suspicious,</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. She goes on to say "It is significant</p> <p>20 to note that neither Sunrise or Harvard</p> <p>21 triggered the algorithms that were in place for</p> <p>22 direct customers because we were looking at</p> <p>23 overall purchase trends for each distributor,</p> <p>24 not reviewing where the distributors were</p>
<p style="text-align: center;">Page 195</p> <p>1 provide you with as much information as</p> <p>2 possible, I have attached a (lengthy) chronology</p> <p>3 of events relating to Mallinckrodt Suspicious</p> <p>4 Order Monitoring."</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. Let me hand you what we've marked as</p> <p>8 Exhibit 19, and you can tell me if that's the</p> <p>9 attachment.</p> <p>10 (Whereupon, Mallinckrodt-Spaulding-19</p> <p>11 was marked for identification.)</p> <p>12 BY MR. GOTTO:</p> <p>13 Q. Exhibit 19 is a multi-page document</p> <p>14 beginning at page MNK-T1_0000477900. Can you</p> <p>15 tell me if that's the chronology that Ms. Harper</p> <p>16 is referring to?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And you're familiar with that</p> <p>19 chronology, right?</p> <p>20 A. At a high level, yes.</p> <p>21 Q. Okay. Did you have occasion ever to</p> <p>22 provide this chronology to DEA?</p> <p>23 A. We met in -- we went and met with DEA.</p> <p>24 We didn't provide a document, I don't recall.</p>	<p style="text-align: center;">Page 197</p> <p>1 sending our product (and our program met CFR</p> <p>2 requirements)."</p> <p>3 And is that the phenomenon you</p> <p>4 testified about earlier today, looking at ship</p> <p>5 to rather than bill to?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. No, that's different.</p> <p>8 BY MR. GOTTO:</p> <p>9 Q. Okay. In what way is this different?</p> <p>10 A. So Karen is referring to downstream</p> <p>11 customers, so those wouldn't have triggered</p> <p>12 because we were only looking at our direct</p> <p>13 shipments to Sunrise and to Harvard. We weren't</p> <p>14 looking at where Harvard was shipping, or</p> <p>15 Sunrise.</p> <p>16 Q. Okay. And she indicates in the last</p> <p>17 sentence of that paragraph that the program has</p> <p>18 now been expanded in October of 2010 to look at</p> <p>19 customers' customers, correct?</p> <p>20 A. Based on this e-mail, yes.</p> <p>21 Q. Okay. And was that your recollection</p> <p>22 as well, that in late 2010 the SOM program was</p> <p>23 expanded to include a review of Mallinckrodt's</p> <p>24 customers' customers?</p>

Page 198	Page 200
<p>1 MR. O'CONNOR: Objection to form.</p> <p>2 A. Only based on this e-mail.</p> <p>3 BY MR. GOTTO:</p> <p>4 Q. You don't otherwise recall that?</p> <p>5 A. No.</p> <p>6 Q. Can you recall at any time in</p> <p>7 connection with suspicious order monitoring you</p> <p>8 personally reviewing information regarding</p> <p>9 Mallinckrodt's customers' customers?</p> <p>10 A. I was involved in reviewing</p> <p>11 chargebacks, but I don't remember when that</p> <p>12 started.</p> <p>13 Q. And that would have given you</p> <p>14 information about Mallinckrodt's customers'</p> <p>15 customers, right?</p> <p>16 A. If they applied and participated in</p> <p>17 chargebacks, yes.</p> <p>18 Q. Okay.</p> <p>19 (Whereupon, Mallinckrodt-Spaulding-20</p> <p>20 was marked for identification.)</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. We've marked as Exhibit 20 a two-page</p> <p>23 document beginning at Bates MNK-T1_0002357150,</p> <p>24 appear to be notes from the 11/1/10 meeting at</p>	<p>1 Q. And what was the reason that you</p> <p>2 wanted to explain the SOM program to the DEA at</p> <p>3 this point?</p> <p>4 A. I don't remember specifically.</p> <p>5 Q. Under "General Feedback from DEA</p> <p>6 Albany," it states "The direct and indirect</p> <p>7 customer data was presented to DEA. DEA was</p> <p>8 alarmed by the data but not surprised."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And were these your notes or</p> <p>12 Mr. Nikolaus's notes?</p> <p>13 A. They were my notes.</p> <p>14 Q. Okay. So when you say they were</p> <p>15 alarmed by the data but not surprised, what do</p> <p>16 you mean? How did they express that?</p> <p>17 A. I remember them looking at the data</p> <p>18 and going "wow." And then a comment by someone</p> <p>19 that was in attendance, I don't remember</p> <p>20 specifically who, saying they're not surprised</p> <p>21 by that.</p> <p>22 Q. What was your reason for providing the</p> <p>23 direct and indirect customer data to the DEA at</p> <p>24 this time?</p>
<p>1 the DEA Albany office.</p> <p>2 Do you recognize those notes?</p> <p>3 A. Yes.</p> <p>4 Q. And it indicates that you and</p> <p>5 Mr. Nikolaus attended the meeting, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And you recall the meeting, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Can you recall other similar meetings</p> <p>10 with the DEA Albany office?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. Similar, meeting with them about this</p> <p>13 topic or about any topic?</p> <p>14 BY MR. GOTTO:</p> <p>15 Q. Well, back that up.</p> <p>16 Did you have regular meetings at the</p> <p>17 DEA's Albany office?</p> <p>18 A. No.</p> <p>19 Q. Okay. So was this meeting requested</p> <p>20 by the DEA?</p> <p>21 A. No, this meeting was requested by</p> <p>22 Mallinckrodt.</p> <p>23 Q. And for what purpose?</p> <p>24 A. To explain to them our SOM program.</p>	<p>1 A. Because we were incorporating</p> <p>2 chargebacks into our SOM program, so when</p> <p>3 explaining the SOM program we showed them what</p> <p>4 we were looking at direct data, and what we were</p> <p>5 looking at indirect data.</p> <p>6 Q. And was this the first time that you</p> <p>7 began to look at the direct and indirect</p> <p>8 customer data?</p> <p>9 MR. O'CONNOR: Objection to form.</p> <p>10 BY MR. GOTTO:</p> <p>11 Q. In this time frame?</p> <p>12 A. I don't remember when I started. We</p> <p>13 were doing it at this time.</p> <p>14 Q. If you look at Exhibit 18, I believe</p> <p>15 Ms. Harper indicated in her e-mail dated</p> <p>16 October 31 that "the program was expanded within</p> <p>17 the last month to our customers' customers." So</p> <p>18 would that indicate that this is -- that the</p> <p>19 meeting occurred on November 1st, right, so</p> <p>20 would that indicate that at this time this was</p> <p>21 when you first began looking at the indirect</p> <p>22 customer data?</p> <p>23 MR. O'CONNOR: Objection to form.</p> <p>24 A. Based on this e-mail. But I don't</p>

Page 202	Page 204
<p>1 remember.</p> <p>2 BY MR. GOTTO:</p> <p>3 Q. Okay. You can set that aside.</p> <p>4 (Whereupon, Mallinckrodt-Spaulding-21</p> <p>5 was marked for identification.)</p> <p>6 BY MR. GOTTO:</p> <p>7 Q. Exhibit 21 is a single-page e-mail</p> <p>8 thread MNK-T1_0000270021. Take a look at that</p> <p>9 e-mail, appears to be an e-mail from you to</p> <p>10 Heather White, and tell me if you recognize it.</p> <p>11 (Witness reviewing document.)</p> <p>12 A. Okay.</p> <p>13 Q. Do you recognize that e-mail?</p> <p>14 A. Yes.</p> <p>15 Q. And Heather White was at the DEA,</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. And what was your reason for providing</p> <p>19 the information in your November 30th e-mail to</p> <p>20 Ms. White?</p> <p>21 A. Because when we spoke to her at the</p> <p>22 on-site meeting we advised that we were sending</p> <p>23 out distributor letters based on the data that</p> <p>24 we had reviewed.</p>	<p>1 Q. Would that information have been</p> <p>2 pertinent to your audit at that time?</p> <p>3 A. If Cedardale had been suspended</p> <p>4 shipping to pharmacies?</p> <p>5 Q. If Cedardale itself had determined</p> <p>6 that it would suspend certain of its customers.</p> <p>7 A. We would have documented that in our</p> <p>8 audit notes.</p> <p>9 Q. That would have been of interest to</p> <p>10 you?</p> <p>11 A. It would have been documented.</p> <p>12 Q. But you don't recall being aware of</p> <p>13 that as you sit here today?</p> <p>14 A. No.</p> <p>15 Q. Do you recall if you made an inquiry</p> <p>16 in that regard as part of the audit?</p> <p>17 A. I'd have to look at my notes.</p> <p>18 Q. Okay.</p> <p>19 (Whereupon, Mallinckrodt-Spaulding-22</p> <p>20 was marked for identification.)</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. Exhibit 22 is a two-page e-mail thread</p> <p>23 beginning at Bates MNK-T1_0001519526. Take a</p> <p>24 moment and tell me if you recognize those</p>
<p>1 Q. And you talk about three distributors,</p> <p>2 Masters, KeySource, Cedardale. I think you</p> <p>3 indicated earlier in your testimony today that</p> <p>4 those are three distributors that were audited</p> <p>5 in approximately this time frame, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And ultimately all of those</p> <p>8 distributors had their DEA licenses terminated,</p> <p>9 didn't they?</p> <p>10 MR. O'CONNOR: Object to the form.</p> <p>11 A. I don't know that they were</p> <p>12 terminated.</p> <p>13 BY MR. GOTTO:</p> <p>14 Q. At least suspended?</p> <p>15 A. I know of Masters and KeySource. I</p> <p>16 don't remember Cedardale.</p> <p>17 Q. Do you recall -- you testified a</p> <p>18 little earlier today regarding the Cedardale</p> <p>19 audit. Do you recall if at the time of the</p> <p>20 Cedardale audit you had any information</p> <p>21 regarding whether Cedardale had suspended sales</p> <p>22 to any of its existing customers?</p> <p>23 A. I don't remember having any of that</p> <p>24 information at that time.</p>	<p>1 e-mails.</p> <p>2 (Witness reviewing document.)</p> <p>3 A. Okay.</p> <p>4 Q. Do you recognize those e-mails?</p> <p>5 A. I don't remember them, no.</p> <p>6 Q. Okay. The main e-mail, the August 6,</p> <p>7 2012 e-mail from you to Heather White, "is a</p> <p>8 list of distributors that we have met with in</p> <p>9 person or by telephone to discuss SOM issues</p> <p>10 within the last twelve months."</p> <p>11 Do you recall having those personal or</p> <p>12 telephonic meetings with the listed</p> <p>13 distributors?</p> <p>14 A. I remember having telecons, yes.</p> <p>15 Q. And what would cause you to have a</p> <p>16 personal or telephonic meeting with a</p> <p>17 distributor regarding SOM issues?</p> <p>18 A. So the SOM team would decide whether</p> <p>19 we needed to do an on-site audit or if we could</p> <p>20 do a telecon in which we'd review with them</p> <p>21 their orders and the data, their chargeback</p> <p>22 data.</p> <p>23 Q. And what is it that would cause the</p> <p>24 team to decide that such an audit or</p>

<p style="text-align: right;">Page 206</p> <p>1 teleconference was required?</p> <p>2 A. I don't remember any specifics why we 3 would.</p> <p>4 Q. Of the parties listed in this e-mail, 5 do you recall how any of these were personal 6 meetings as compared to teleconferences?</p> <p>7 A. In 2012, no, because some of the 8 on-site audits were conducted by people in 9 corporate, so I don't remember specific. I 10 remember doing -- I was only involved in the 11 Cedardale audit on-site, and I remember being 12 involved in telecons, but which ones 13 specifically, I'd have to look at notes.</p> <p>14 MR. GOTTO: Okay. Why don't we take a 15 break.</p> <p>16 THE VIDEOGRAPHER: The time is 17 2:28 p.m., and we're off the record.</p> <p>18 (Whereupon, a recess was taken.)</p> <p>19 THE VIDEOGRAPHER: The time is 20 2:42 p.m., and we're on the record.</p> <p>21 (Whereupon, Mallinckrodt-Spaulding-23 22 was marked for identification.)</p> <p>23 BY MR. GOTTO:</p> <p>24 Q. Ms. Spaulding, we've marked as</p>	<p style="text-align: right;">Page 208</p> <p>1 centralized place between all three sites to 2 document any correspondence that we had with 3 DEA, so I feel the need to clarify that even 4 though we called them SOM contacts or inquiry, 5 they were not always indicative of a suspicious 6 order. It was part of the overall umbrella 7 program of suspicious order monitoring.</p> <p>8 Q. Okay. And so what would be an example 9 of something that's under that overall umbrella 10 but was not indicative of the suspicious order?</p> <p>11 A. So, for example, in this report 11-01, 12 this was the ARCOS unit contacting me about two 13 NDC errors -- or I'm sorry, contacting Mary 14 Lewis and Webster Groves. One that was specific 15 to me was line 5, so report 11-03 was to contact 16 DI Heather White because we had a complaint 17 about Methadose 40-milligram bottle complaints.</p> <p>18 Q. Okay. And then one of the attachments 19 is -- it's called a DEA Suspicious Order 20 Monitoring Report?</p> <p>21 A. Yes.</p> <p>22 Q. And what is that document?</p> <p>23 A. So this was a template that we were 24 using to how we would document a formal</p>
<p style="text-align: right;">Page 207</p> <p>1 Exhibit 23 a multi-page document beginning at 2 Bates MNK-T1_0000289371. It's an e-mail along 3 with an attachment. Please take a look at that 4 and tell me if you recognize it.</p> <p>5 I guess it actually has a series of 6 attachments, I should say.</p> <p>7 (Witness reviewing document.)</p> <p>8 A. Okay.</p> <p>9 Q. Do you recognize those documents?</p> <p>10 A. No, I don't remember them, only based 11 on the e-mail.</p> <p>12 Q. Okay. So your e-mail, your 13 October 18th e-mail to Ms. Harper, any reason to 14 doubt you sent that?</p> <p>15 A. No.</p> <p>16 Q. And you make reference in your e-mail 17 to "tried several different ways to make a 18 report that we could use across sites to be 19 consistent in our practices."</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. So can you describe for me what you 23 were trying to accomplish in this regard?</p> <p>24 A. So we were looking to make a</p>	<p style="text-align: right;">Page 209</p> <p>1 suspicious order.</p> <p>2 Q. Okay. And so this is not a DEA form, 3 right? This is something you -- or Mallinckrodt 4 created?</p> <p>5 A. Correct. This one is -- it says up at 6 the top is an example only.</p> <p>7 Q. Okay. You can set that aside.</p> <p>8 (Whereupon, Mallinckrodt-Spaulding-24 9 was marked for identification.)</p> <p>10 BY MR. GOTTO:</p> <p>11 Q. Exhibit 24 is a multi-page document 12 beginning at MNK-T1_0000282467, appears to be an 13 e-mail you prepared attaching the notes of an 14 HDMA conference that you attended.</p> <p>15 Could you take a look at that and 16 confirm for me, if you can, that that's what the 17 exhibit consists of?</p> <p>18 (Witness reviewing document.)</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Do you recall this conference?</p> <p>21 A. Vaguely. Not in detail, but yes.</p> <p>22 Q. Did you make a practice of keeping 23 notes like these at each conference you went to 24 and then memorializing them?</p>

Page 210	Page 212
<p>1 A. Not every conference, only if I was 2 asked to produce a conference or a trip report. 3 Q. Okay. And who would have asked you to 4 do that? 5 A. My manager at the time. 6 Q. If you turn to the next-to-last page 7 of the document, the one that ends in Bates 8 473 -- I guess actually starting at the bottom 9 of the third-to-last page that begins at Bates 10 472, there's a reference to a presentation by a 11 David Durkin regarding controlled substance 12 monitoring, 2011 update. 13 Do you see that? 14 A. Yes. 15 Q. And the main bullet items, the third 16 one on the following page is "Reviewed the 17 12/2007 DEA Letter to registrants." 18 Do you see that? 19 A. Give me one moment, please. 20 Q. Sure. 21 (Witness reviewing document.) 22 A. I'm sorry, which bullet were you -- 23 Q. There's -- the second main bullet on 24 the page that ends in 473 says "Reviewed the</p>	<p>1 or anyone else at Mallinckrodt? 2 A. Go over them? I sent them to her, but 3 I didn't -- I don't know that I reviewed or 4 discussed them with her. 5 Q. Okay. On the second page of your 6 notes up at the top where it says "SOM System 7 Recommendations - Total SOM Solution," do you 8 see that? 9 A. Yes. 10 Q. The second item is "Determine 11 legitimacy before shipping for each and every 12 order." 13 Do you see that? 14 A. Yes. 15 Q. Did you understand at this time that 16 an SOM program -- that part of an effective SOM 17 program should be that before an order that was 18 identified -- that was questioned in any way 19 shipped, a determination needed to be made as to 20 whether or not it was suspicious? 21 MR. O'CONNOR: Objection to form. 22 A. At this time back in 2011 did I know 23 that? 24 BY MR. GOTTO:</p>
<p>1 12/2007 DEA Letter to registrants." 2 Do you see that? 3 A. Yes. 4 Q. And that's the letter from 5 Mr. Rannazzisi that we looked at a little 6 earlier today, correct? 7 A. I'm not looking at the date, but I 8 believe so, yes. 9 Q. Okay. You can set that aside. 10 (Whereupon, Mallinckrodt-Spaulding-25 11 was marked for identification.) 12 BY MR. GOTTO: 13 Q. Exhibit 25 is a multi-page document 14 bearing Bates MNK-T1_0000283244, appears to be 15 an e-mail you prepared transmitting notes you 16 took at a Buzzeo webinar in April of 2011. If 17 you could take a look at that and confirm for me 18 that that's what those materials are. 19 A. Yes. 20 Q. Okay. Do you recall this particular 21 webinar? 22 A. Not this one, no. 23 Q. The notes that you took here, did you 24 have occasion to go over these with Ms. Harper</p>	<p>1 Q. Yes. 2 A. I don't know if I knew it at the time. 3 I mean, I understood what it says when they 4 spoke of it. 5 Q. Okay. Do you have an understanding as 6 to whether in this time frame in 2011 7 Mallinckrodt had procedures in place to assure 8 that orders that had been identified as peculiar 9 or unusual would not be shipped until it was 10 determined whether or not there would be -- they 11 were suspicious? 12 MR. O'CONNOR: Objection to form. 13 A. So based on our review of documents 14 prior in 2010, we discussed that we were 15 reviewing orders before shipping. 16 BY MR. GOTTO: 17 Q. Do you know if there were ever 18 occasions when an order that was identified as 19 peculiar or unusual was shipped before the 20 determination was made as to whether it was 21 suspicious? 22 A. Not by me, but I wasn't doing -- I'm 23 not aware. I wasn't doing the review. 24 Q. Do you recall in 2010 there being a</p>

<p style="text-align: right;">Page 214</p> <p>1 change to the algorithm whereby the comparison 2 of an order to the prior year's ordering pattern 3 was changed from whether it was more than two 4 times the average to whether it was more than 5 three times the average?</p> <p>6 A. I remember that there was a change. I 7 don't remember whether it was specifically in 8 2010 or not.</p> <p>9 Q. Okay. But you do remember that 2X to 10 3X change being made at some point?</p> <p>11 A. Yes.</p> <p>12 Q. Do you remember what the reason was 13 for that change?</p> <p>14 A. No.</p> <p>15 Q. Were you involved in the decision to 16 make that change?</p> <p>17 A. I would have been on the SOM team that 18 discussed the change, but it would have been 19 approved by the management.</p> <p>20 Q. Do you remember who suggested the 21 change?</p> <p>22 A. No.</p> <p>23 Q. And you don't remember any of the 24 reasons that were offered in support of it?</p>	<p style="text-align: right;">Page 216</p> <p>1 Q. Right. But you were, as of November, 2 2010, you were reviewing chargeback data as part 3 of the SOM process, correct?</p> <p>4 A. Yes.</p> <p>5 Q. And so my question is, once you 6 started reviewing the chargeback data, did that 7 result in the identification of any orders as 8 peculiar or unusual or suspicious under the SOM 9 program?</p> <p>10 A. No, because there's no way to directly 11 tie a chargeback order credit to a direct order.</p> <p>12 Q. And so how was the chargeback data 13 used as part of the SOM program from and after 14 November of 2010?</p> <p>15 A. To review if a downstream customer, so 16 a customer's customer, may pose a risk to bring 17 that attention to the down-direct customer.</p> <p>18 Q. And how would you identify as part of 19 the chargeback review the potential for that 20 downstream customer to pose a risk?</p> <p>21 A. So based on the red flags and the 22 enforcement action in comments from DEA at 23 training sessions through the DEA seminars, we 24 developed a red flags list, and we would look at</p>
<p style="text-align: right;">Page 215</p> <p>1 A. No, not specifically. 2 (Whereupon, Mallinckrodt-Spaulding-26 3 was marked for identification.)</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. Exhibit 26 is a two-page document 6 beginning at Bates MNK-T1_0000288483, appears to 7 be a letter from you to Heather White at the 8 DEA. And take a look and tell me if you can 9 confirm that that's a letter that you sent on or 10 about November 1 of 2010.</p> <p>11 (Witness reviewing document.)</p> <p>12 A. Yes, this is a letter I sent.</p> <p>13 Q. Okay. And this is notifying Ms. White 14 of the inclusion in the SOM program of review of 15 chargeback data, correct?</p> <p>16 A. Yes.</p> <p>17 Q. And do you recall, after the 18 chargeback data review was included as part of 19 the SOM program, were there orders that were 20 identified as peculiar or unusual solely as a 21 result of the chargeback review?</p> <p>22 A. So I don't think I understand.</p> <p>23 Chargeback are not orders. Chargeback are 24 downstream.</p>	<p style="text-align: right;">Page 217</p> <p>1 chargebacks to see if a pharmacy had a large 2 quantity, we would then ask the distributor for 3 due diligence and ask them to check for any of 4 these red flags as part of the review.</p> <p>5 Q. So is it fair to say Mallinckrodt 6 itself would not take any action directly with 7 respect to this indirect customer, but would 8 instead provide information to Mallinckrodt's 9 direct customer?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. We would do both. So we would work 12 with the distributor to bring to their attention 13 that we're potentially seeing chargebacks, 14 because a distributor would only see what they 15 sold, they wouldn't see if there was other 16 distributors selling to them. And if the SOM 17 team determined that the pharmacy was a 18 significant risk, they would issue a restriction 19 in which that pharmacy could no longer apply for 20 chargebacks.</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. Okay. So the pharmacy would -- it 23 could continue to buy from a Mallinckrodt 24 distributor, but it could not apply for a</p>

Page 218	Page 220
<p>1 chargeback?</p> <p>2 A. Correct.</p> <p>3 Q. So the chargebacks, were they applied</p> <p>4 for by the pharmacies or by the distributor?</p> <p>5 A. The chargeback is applied by the</p> <p>6 distributor to Mallinckrodt on behalf of the</p> <p>7 pharmacy.</p> <p>8 Q. So it would have been possible for</p> <p>9 Mallinckrodt to inform the distributor that</p> <p>10 sales should not be made to that pharmacy, as</p> <p>11 compared to stating that Mallinckrodt would not</p> <p>12 pay chargebacks to that -- related to that</p> <p>13 pharmacy, correct?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. No, we can't dictate who a distributor</p> <p>16 sells to and who they don't sell to.</p> <p>17 BY MR. GOTTO:</p> <p>18 Q. So if you knew that a distributor, for</p> <p>19 example, was selling to a non-registrant, you</p> <p>20 could tell the distributor, you need to stop</p> <p>21 doing that or we can't sell to you anymore,</p> <p>22 correct?</p> <p>23 A. If we knew that they were selling to a</p> <p>24 non-DEA registrant, I believe we would alert DEA</p>	<p>1 get Mallinckrodt product.</p> <p>2 Q. And that's true, though, if you say</p> <p>3 we're not going to honor chargebacks, that</p> <p>4 pharmacy can continue to buy Mallinckrodt</p> <p>5 products even through that distributor, just not</p> <p>6 going to -- the chargeback won't be honored,</p> <p>7 correct?</p> <p>8 A. Correct. It's a financial</p> <p>9 disincentive not to sell Mallinckrodt product,</p> <p>10 but we can't say who they can or can't sell to.</p> <p>11 Q. Was the result of any chargeback data</p> <p>12 review ever provided to the DEA?</p> <p>13 A. Can you say at that again, please?</p> <p>14 Q. Yes.</p> <p>15 So you engaged in -- from November,</p> <p>16 2010 forward you were reviewing chargeback data</p> <p>17 as part of an evaluation as to whether there</p> <p>18 were red flags with respect to some indirect --</p> <p>19 with respect to indirect customers, correct?</p> <p>20 A. Yes. If we restricted a pharmacy from</p> <p>21 chargebacks, we notified DEA.</p> <p>22 Q. Okay. And was there any follow-up</p> <p>23 from DEA that you can recall when there was any</p> <p>24 such notification given?</p>
Page 219	Page 221
<p>1 to that.</p> <p>2 Q. And so if you knew that a distributor</p> <p>3 was selling to a pharmacy as to which there was</p> <p>4 sufficient red flags to where Mallinckrodt</p> <p>5 decided that it would no longer pay chargebacks</p> <p>6 with respect to that pharmacy, Mallinckrodt</p> <p>7 could have notified the distributor that if the</p> <p>8 distributor continued to sell to that pharmacy</p> <p>9 Mallinckrodt wouldn't sell to the distributor</p> <p>10 anymore?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 BY MR. GOTTO:</p> <p>13 Q. Right?</p> <p>14 A. No, because then we could potentially</p> <p>15 jeopardize legitimate people from not getting</p> <p>16 their medicines. We prohibited the chargebacks</p> <p>17 as a financial disincentive to not sell</p> <p>18 Mallinckrodt to a pharmacy that we considered a</p> <p>19 risk. But we can't control the distributors and</p> <p>20 who they sell to. We have no influence</p> <p>21 whatsoever on who the customer base of any one</p> <p>22 distributor is. And if we had -- say you can't</p> <p>23 sell to that pharmacy anymore, that pharmacy</p> <p>24 could potentially go to another distributor and</p>	<p>1 A. Not that I can think of.</p> <p>2 Q. What was the nature of the</p> <p>3 notification? What did you tell DEA?</p> <p>4 A. We have a letter that we would notify</p> <p>5 sent to DEA saying these pharmacies have been</p> <p>6 restricted from Mallinckrodt chargebacks because</p> <p>7 they exhibit indicators of diversion.</p> <p>8 Q. You can set that aside.</p> <p>9 (Whereupon, Mallinckrodt-Spaulding-27</p> <p>10 was marked for identification.)</p> <p>11 BY MR. GOTTO:</p> <p>12 Q. Exhibit 27 is a multi-page document</p> <p>13 beginning at Bates MNK-T1_0000422189. It's an</p> <p>14 e-mail thread from late 2010 into January of</p> <p>15 2011. Take a moment and tell me if you</p> <p>16 recognize those e-mails.</p> <p>17 (Witness reviewing document.)</p> <p>18 A. Okay.</p> <p>19 Q. Do you recognize these e-mails?</p> <p>20 A. No.</p> <p>21 Q. Okay. So the earliest e-mails in the</p> <p>22 thread are an exchange between Ms. Harper and</p> <p>23 Carol Svejkosky --</p> <p>24 A. Yeah, Svejkosky.</p>

<p style="text-align: right;">Page 222</p> <p>1 Q. Thank you. S-V-E-J-K-O-S-K-Y, just 2 like it sounds. 3 -- in which Ms. Harper is requesting 4 certain state concentration and customer 5 sourcing data, correct? 6 A. Yes. 7 Q. And is that data that ultimately you 8 came to be supplied with regularly? 9 A. Yes. 10 Q. Okay. And did that become part of the 11 SOM program, reviewing that data on a monthly 12 basis? 13 A. Yes. 14 Q. What was the state concentration 15 report that Ms. Harper requests? 16 A. It looks at oxycodone 50-milligram and 17 oxycodone 30-milligram by state instead of by 18 pharmacy. 19 Q. And do you know what the reason was 20 for conducting that review? 21 A. Based on at this time the enforcement 22 action and the knowledge around Florida and 23 other states being of concern. 24 Q. Okay. All right. You can set that</p>	<p style="text-align: right;">Page 224</p> <p>1 A. No, I couldn't guess what she was 2 referring to. 3 Q. Okay. So if you look at the first 4 e-mail in the thread from Thanh Churchin, 5 "Susan, can you check on this lot number for 6 me," giving a case number. "The lot number came 7 from a trash pull that IRS did." 8 Do you know what "lot number" means in 9 this context? 10 A. Yes. It's the lot number that 11 Mallinckrodt produced for that particular batch. 12 Q. Okay. And what would be the reason 13 for using that lot number? 14 MR. O'CONNOR: Objection to form. 15 BY MR. GOTTO: 16 Q. What information would that give you? 17 A. We could trace the lot number to see 18 who we sold it to, but then they would have to 19 go to who we sold it to to trace who they sold 20 it to. 21 Q. Okay. And so turning back to 22 Ms. White's e-mail where she says "I know the 23 standard answer regarding lot numbers," was the 24 standard answer that you would give that</p>
<p style="text-align: right;">Page 223</p> <p>1 aside. 2 (Whereupon, Mallinckrodt-Spaulding-28 3 was marked for identification.) 4 BY MR. GOTTO: 5 Q. Exhibit 28 is a two-page e-mail thread 6 beginning at Bates MNK-T1_0000485790, e-mails 7 from November of 2010. Take a moment and tell 8 me if you recall these e-mails. 9 (Witness reviewing document.) 10 A. Okay. 11 Q. Do you recognize these e-mails? 12 A. I don't remember them. 13 Q. Okay. If you look at Ms. White's 14 e-mail at the bottom of the first page to you on 15 November 18th, she says "I know the standard 16 answer regarding lot numbers. Can you please 17 tell me which distributors this was sent to and 18 if you had any chargebacks for the product in 19 the Fort Lauderdale area? We can get an 20 Administrative Subpoena if you need one." 21 Do you see that? 22 A. Yes. 23 Q. So do you know what she meant by "the 24 standard answer regarding lot numbers"?</p>	<p style="text-align: right;">Page 225</p> <p>1 information if there was -- in response to a 2 subpoena? 3 A. I don't know what she meant. 4 Q. Do you recall ever informing Ms. White 5 or anyone else at the DEA that certain 6 information they sought would be provided only 7 in response to a subpoena? 8 A. We usually request a subpoena if they 9 want anything in writing, so it's pretty 10 standard. 11 Q. Okay. And so there would be times 12 when you would give them verbal information, but 13 if they wanted that information in writing you'd 14 tell them they needed to issue a subpoena? 15 A. Not during a -- not a shipping history 16 report. 17 Q. You would not require a subpoena for 18 that? 19 A. No. I'm sorry. We would require -- I 20 would not give them that information verbally. 21 Q. Okay. And what's the reason for that? 22 A. Just any information that's provided 23 to DEA always goes through our legal department. 24 Q. Well, there was certain information</p>

Page 226	Page 228
<p>1 you would give DEA verbally, that if they asked 2 for it in writing you'd require a subpoena, 3 correct?</p> <p>4 A. The information that we would give to 5 them verbally would be routine information that 6 they would ask regarding a process or a high 7 level question. Anything that was documented or 8 in detail like a shipping report would require a 9 subpoena.</p> <p>10 Q. Okay. So your November 18th e-mail to 11 Karen Harper says "I can run a report on where 12 we ship this lot number to. Does the chargeback 13 system refer to lot numbers? If so" you can get 14 a report, please. I'm sorry, "If so, can you 15 get a report please."</p> <p>16 So I take it at this time in November 17 of 2010 you didn't know if the chargeback system 18 contained the lot numbers for orders, correct?</p> <p>19 A. Correct. Because what we looked at 20 were reports that were generated from the 21 chargeback system.</p> <p>22 Q. Okay. And so the -- what information 23 were you able to determine from reviewing a lot 24 number?</p>	<p>1 Q. Do you recall that e-mail? 2 A. Vaguely, yes. 3 Q. Okay. And then you respond to him on 4 July 6th "Would you like me to run a lot trace 5 report ASAP?" 6 A. Correct. 7 Q. And he responds "Yes." You run the 8 report. Is the attachment to the e-mail the 9 report?</p> <p>10 A. Yes. 11 Q. And you say in your e-mail total 12 quantity of bottles. You say "Lot beam for 13 release." 14 What does that mean? 15 A. It means when it is released from our 16 quality control labs and able to be shipped to 17 market. 18 Q. Okay. And then "Shipped from DC." 19 What is DC? 20 A. Distribution center. 21 Q. Okay. On the dates, "and entire lot 22 is depleted. 8 customers in total, 1 in 23 Florida." 24 And then the eight customers are</p>
<p style="text-align: center;">Page 227</p> <p>1 A. Where we shipped it to. 2 (Whereupon, Mallinckrodt-Spaulding-29 3 was marked for identification.)</p> <p>4 BY MR. GOTTO:</p> <p>5 Q. Exhibit 29 is a multi-page document 6 beginning at Bates MNK-T1_0000561060, appears to 7 be an e-mail exchange between you and 8 Mr. Ratliff concerning a lot trace report. Take 9 a look at those e-mails, tell me if you 10 recognize them. 11 (Witness reviewing document.)</p> <p>12 A. Okay.</p> <p>13 Q. Okay. And so the first e-mail in the 14 thread is from Mr. Ratliff, down at the bottom 15 of the first page onto the second page, from 16 Mr. Ratliff to you and Mr. Nikolaus, where he 17 says "Oxy, lot," and gives a number, "is being 18 transported from Florida to Eastern Tennessee in 19 fairly significant quantities. They have 20 original bottles and are currently looking for 21 the source of loss in Florida. I will be 22 receiving additional information soon." 23 Do you see that? 24 A. Yes.</p>	<p style="text-align: center;">Page 229</p> <p>1 listed on the attachment, correct? 2 A. Yes. 3 Q. And so the attachment, is this typical 4 of the information that a lot trace report would 5 give you? 6 A. It's the exact information. 7 Q. Okay. You can set that aside. 8 (Whereupon, Mallinckrodt-Spaulding-30 9 was marked for identification.)</p> <p>10 BY MR. GOTTO:</p> <p>11 Q. Exhibit 30 is a two-page document 12 beginning at Bates MNK-T1_0000371673, and 13 appears to be an e-mail exchange between you and 14 Ms. Harper in June of 2010 concerning a DEA and 15 local law enforcement inquiry. Tell me if you 16 recognize those e-mails. 17 (Witness reviewing document.)</p> <p>18 A. Okay.</p> <p>19 Q. Do you recognize those e-mails? 20 A. Yes. 21 Q. Okay. So in your June 17th e-mail to 22 Ms. Harper, in the first paragraph you say that 23 in recent months you "received several inquiries 24 from both local law enforcement and DEA...in the</p>

Page 230	Page 232
<p>1 State of Florida and surrounding states 2 regarding lot trace shipping histories." 3 You go on a little later in the 4 paragraph to say "In many of these inquiries, I 5 noticed that Sunrise Wholesalers was one of our 6 customers who had received the lot in question 7 by the investigating officer. I did not always 8 divulge that information unless requested 9 specifically by the individual and never 10 provided any information in writing as they were 11 advised that they would need to send a subpoena 12 to our legal department if they needed 13 documentation of any kind."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. So what was your reason for not 17 divulging that information to law enforcement 18 unless specifically requested?</p> <p>19 A. I don't remember the specifics of this 20 situation back in 2010, but it's usually policy 21 we don't discuss that information over the 22 phone.</p> <p>23 Q. But if you had -- if the law 24 enforcement agent had specifically requested it,</p>	<p>1 Q. You could have informed them of the 2 information without the specific request, 3 though, right?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. If they didn't request it, I didn't 6 know what they were looking for, and I didn't 7 assume or presume to know what they were looking 8 for.</p> <p>9 BY MR. GOTTO:</p> <p>10 Q. Did Ms. Harper -- we see her e-mail in 11 response. Apart from her e-mail, did she ever 12 communicate with you with respect to your 13 practice of how to respond to law enforcement 14 inquiries as you describe it in that first 15 paragraph?</p> <p>16 A. I don't understand the question.</p> <p>17 Q. Sure.</p> <p>18 You describe in your first paragraph 19 of your June 17th e-mail how you handled 20 inquiries from law enforcement, and this point 21 of not divulging information unless specifically 22 requested. Did Ms. Harper ever respond to you 23 with respect to that practice to say either it 24 was the right way to handle the inquiries or to</p>
<p>1 you would have divulged it over the phone, is 2 that right?</p> <p>3 A. I may have pointed them in the right 4 direction to help with their investigation.</p> <p>5 Q. And is there any reason that you would 6 require them to specifically request the 7 information before you would help them with the 8 investigation?</p> <p>9 MR. O'CONNOR: Object to form.</p> <p>10 A. Because we didn't want to assume what 11 they were looking for, and they didn't always 12 give us details, so we didn't assume what they 13 were looking for. So unless they specifically 14 asked me, I didn't provide the information.</p> <p>15 BY MR. GOTTO:</p> <p>16 Q. Was it your intention to cooperate 17 with law enforcement when you received inquiries 18 of this nature?</p> <p>19 A. To the best of my ability, yes.</p> <p>20 Q. And did you feel that requiring them 21 to specifically request the information before 22 you would divulge it was cooperating to the best 23 of your ability?</p> <p>24 A. Yes.</p>	<p>1 suggest some other way to handle them?</p> <p>2 MR. O'CONNOR: Objection to form.</p> <p>3 A. So those were conversations with our 4 legal department.</p> <p>5 MR. O'CONNOR: And of course, I 6 instruct the witness not to answer to the extent 7 it gets into conversations with legal.</p> <p>8 BY MR. GOTTO:</p> <p>9 Q. Okay. So -- and you can just answer 10 this yes or no. Apart from conversations with 11 legal counsel, did you ever have any 12 conversations with Ms. Harper on this topic of 13 how you responded to inquiries from law 14 enforcement of the type you describe in this 15 paragraph?</p> <p>16 A. Not that I remember.</p> <p>17 Q. And again, apart from conversations 18 with counsel, did you have discussions with 19 anyone else at Mallinckrodt with respect to how 20 you responded to law enforcement inquiries as 21 you describe in this paragraph?</p> <p>22 A. With the security director at this 23 time.</p> <p>24 Q. And who was that?</p>

<p style="text-align: right;">Page 234</p> <p>1 A. Bill Ratliff.</p> <p>2 Q. And what can you recall of that</p> <p>3 conversation?</p> <p>4 A. Basically as I previously stated, we</p> <p>5 don't assume what they're looking for, we don't</p> <p>6 know the facts of their case, and we answer the</p> <p>7 questions to the best of our ability. But we</p> <p>8 don't always know who we're talking to over the</p> <p>9 phone, so if they are looking for detailed</p> <p>10 information or want documentation they have to</p> <p>11 send a subpoena so that it goes through the</p> <p>12 proper channels.</p> <p>13 Q. Okay. And did Mr. Ratliff give you</p> <p>14 any feedback as far as that approach, either</p> <p>15 confirming it or suggesting a change?</p> <p>16 A. I was cautioned not to give out</p> <p>17 information over the phone because we don't know</p> <p>18 who we're talking to over the phone.</p> <p>19 Q. The practice that you described</p> <p>20 regarding when you would give information, when</p> <p>21 you would require a subpoena, was there a</p> <p>22 written policy in place at Mallinckrodt to that</p> <p>23 effect?</p> <p>24 A. I don't believe there's a written</p>	<p style="text-align: right;">Page 236</p> <p>1 uncovered, do you recall?</p> <p>2 A. The customer called us and said they</p> <p>3 had received C2 product.</p> <p>4 Q. Okay. And who was Brenda Rehkop?</p> <p>5 R-E-H-K-O-P.</p> <p>6 A. Customer service rep.</p> <p>7 Q. Were you able to determine how it came</p> <p>8 to be that the product was shipped to Masters</p> <p>9 after they had been put on hold?</p> <p>10 A. It was a timing thing. There was an</p> <p>11 order picked and packed in the warehouse already</p> <p>12 at the time that customer service was notified</p> <p>13 to put the orders on hold.</p> <p>14 Q. So on the first page of the exhibit,</p> <p>15 your e-mail dated July 13, 2011, you say "I</p> <p>16 completely understand and will not disclose.</p> <p>17 It's impossible to manage so many accounts</p> <p>18 manually due to these circumstances that are</p> <p>19 beyond our control."</p> <p>20 What were you referring to there in</p> <p>21 terms of being impossible to manage so many</p> <p>22 accounts manually?</p> <p>23 A. So it was an assumption on my part</p> <p>24 that they have multiple accounts in which</p>
<p style="text-align: right;">Page 235</p> <p>1 policy. I believe it was through verbal</p> <p>2 training.</p> <p>3 Q. And who gave you that verbal training?</p> <p>4 A. Our legal department.</p> <p>5 Q. Okay. You can set that aside.</p> <p>6 (Whereupon, Mallinckrodt-Spaulding-31</p> <p>7 was marked for identification.)</p> <p>8 BY MR. GOTTO:</p> <p>9 Q. Exhibit 31 is a multi-page e-mail</p> <p>10 thread bearing Bates MNK-T1_0005424123. These</p> <p>11 are e-mails from July of 2011. There were</p> <p>12 several e-mails here. I have a couple of</p> <p>13 questions for you really on the first page.</p> <p>14 (Witness reviewing document.)</p> <p>15 A. Okay.</p> <p>16 Q. Do you recognize those e-mails?</p> <p>17 A. I vaguely recall them, yes.</p> <p>18 Q. Okay. What do you recall about them?</p> <p>19 A. This was in the time that we were</p> <p>20 stopping shipments to Masters and putting their</p> <p>21 account on hold, and there was a system error in</p> <p>22 which some material that was shipped was not</p> <p>23 supposed to be.</p> <p>24 Q. Okay. And how was that error</p>	<p style="text-align: right;">Page 237</p> <p>1 they're releasing orders daily for clinics,</p> <p>2 because at this time we shipped clinic orders</p> <p>3 same day. They had orders that were coming in.</p> <p>4 This was at the time that there was action going</p> <p>5 on, I believe, with KeySource and Masters at the</p> <p>6 same time, and we were trying to stop orders in</p> <p>7 transit because the ISO had been issued. And</p> <p>8 there was just multiple balls in the air</p> <p>9 juggling all at one time, and this one order</p> <p>10 fell through the cracks.</p> <p>11 Q. When you say that the order fell</p> <p>12 through the cracks, were you able to ascertain</p> <p>13 who had authorized the shipment to be made?</p> <p>14 A. Yes.</p> <p>15 Q. And who was that?</p> <p>16 A. It was a CSR who released the order.</p> <p>17 Q. And who was it?</p> <p>18 A. Cheryl Nelson.</p> <p>19 Q. Were there any changes made to</p> <p>20 practices or policies to assure that this sort</p> <p>21 of mistake wouldn't happen in the future?</p> <p>22 A. Yes.</p> <p>23 Q. What were they?</p> <p>24 A. So instead of the customer service rep</p>

Page 238	Page 240
<p>1 changing -- being able to change the credit 2 limit to prevent it from shipping, that now has 3 to be done by a separate department that manages 4 the customer accounts, taking that 5 responsibility off from the CSRs. 6 Q. Do you recall in any of the 7 DEA-sponsored seminars or Buzzeo programs that 8 you attended discussions regarding the 9 involvement of either customer service personnel 10 or sales personnel in the suspicious order 11 monitoring program? 12 MR. O'CONNOR: Objection to form. 13 A. I recall at a Buzzeo conference them 14 saying that it's not in the best interest of a 15 company for finance people to be involved in SOM 16 perspective to eliminate that optic of 17 impropriety. 18 BY MR. GOTTO: 19 Q. Okay. And do you recall any similar 20 observation you made with respect to involvement 21 of sales personnel in SOM? 22 A. No, because we have to rely on sales 23 personnel to provide us information sometimes. 24 Q. You can set that aside.</p>	<p>1 correct? 2 A. Yes, based on this e-mail. 3 Q. So had Mallinckrodt requested of 4 Cedardale that Cedardale refrain from selling to 5 specific identified pharmacies? 6 A. Based on this e-mail, yes. 7 Q. Okay. You don't independently recall 8 that? 9 A. No. 10 Q. Do you recall there being other 11 situations in which Mallinckrodt made requests 12 of its distributors not to sell to particular 13 indirect customers? 14 A. No. 15 Q. And then Mr. Picciano goes on to 16 provide information regarding Cedardale's SOM 17 program, correct? 18 A. Yes. 19 Q. And this appears to be before you 20 conducted the on-site audit, correct? 21 A. Yes. 22 Q. And in your March 23rd e-mail to 23 Ms. Harper, you say you reviewed the attached 24 documents, "continue to believe Cedardale needs</p>
<p style="text-align: center;">Page 239</p> <p>1 (Whereupon, Mallinckrodt-Spaulding-32 2 was marked for identification.) 3 BY MR. GOTTO: 4 Q. Exhibit 32 is a two-page e-mail thread 5 with the numbers MNK-T1_0000282686, e-mails from 6 March of 2011 concerning suspicious order 7 monitoring. Tell me if you recognize those 8 e-mails. 9 (Witness reviewing document.) 10 A. Yes. 11 Q. So the earliest e-mail in the thread 12 is from a David Picciano to Karen Harper. 13 And do you know who Mr. Picciano know 14 was? 15 A. Yes. 16 Q. Who was he? 17 A. He's the director of regulatory 18 compliance for Cedardale. 19 Q. Okay. And he says this in his e-mail, 20 "Cedardale Distributors...is willing to comply 21 with Covidien's request that we refrain from 22 selling Mallinckrodt's 15-milligram and 23 30-milligram oxycodone tablets to the Florida 24 based pharmacies listed on Attachment 1,"</p>	<p style="text-align: center;">Page 241</p> <p>1 more work around their SOM program." 2 So was your e-mail prior to the 3 on-site audit? 4 A. My e-mail, no. My e-mail was after 5 their audit in which he sent me those SOPs. 6 Because when we were there for the audit we 7 advised him that he might want to look at making 8 them more robust. 9 Q. Okay. So the SOPs are -- is that 10 what's referenced in -- are you making reference 11 to what's in the November 15th e-mail? 12 A. No. So if you look at the subject 13 line, you can tell it changes with the March, 14 2011 e-mail from my e-mail to Karen with a CC to 15 Rich. 16 Q. Okay. 17 A. And that's where I'm sending her the 18 SOPs that David Picciano has sent to me. 19 Q. I see. Okay. 20 And at that point you concluded that 21 their SOM program was still insufficient, 22 correct? 23 A. Still weak, yes. 24 Q. All right. You can set that aside.</p>

Page 242	Page 244
<p>1 (Whereupon, Mallinckrodt-Spaulding-33 2 was marked for identification.)</p> <p>3 BY MR. GOTTO:</p> <p>4 Q. Exhibit 33 is a one-page document, 5 MNK-T1_0000290887, additional e-mails relating 6 to the Cedardale audit, and these are in January 7 of 2011.</p> <p>8 A. Yes.</p> <p>9 MR. O'CONNOR: Counsel, I apologize, 10 can we go off the record for a minute?</p> <p>11 MR. GOTTO: You bet.</p> <p>12 THE VIDEOGRAPHER: The time is 13 3:35 p.m., we're off the record.</p> <p>14 (Off the record discussion.)</p> <p>15 THE VIDEOGRAPHER: The time is 16 3:36 p.m., and we're on the record.</p> <p>17 (Whereupon, Mallinckrodt-Spaulding-34 18 was marked for identification.)</p> <p>19 BY MR. GOTTO:</p> <p>20 Q. Exhibit 34 is a one-page e-mail 21 thread, MNK-T1_0003044340. Take a moment to 22 look at those e-mails, if you would, and tell me 23 if you recognize them.</p> <p>24 (Witness reviewing document.)</p>	<p>1 unfamiliar of the inner workings of quota, and 2 we explained how St. Louis plant receives 3 manufacturing quota, we receive procurement 4 quota, and that our quota ultimately turns into 5 product that we send to the market.</p> <p>6 BY MR. GOTTO:</p> <p>7 Q. Okay. So how did the suspicious order 8 monitoring program relate to that?</p> <p>9 A. So I can't assume what DEA wanted to 10 know or how it ties in. We could just explain 11 our program.</p> <p>12 Q. Okay. I'm just -- since this is your 13 e-mail, I'm just wondering when you said 14 "provide information on the SOM and how it 15 relates to quota," was there information that 16 comes to your mind as being -- that you provided 17 in response to that request?</p> <p>18 A. I don't remember specific information 19 that was provided or if there was a 20 presentation, only that we explained the quota 21 process and we reviewed our suspicious order 22 monitoring program, and that we can't ship 23 anything to the market that we haven't been 24 granted quota for.</p>
Page 243	Page 245
<p>1 A. Okay.</p> <p>2 Q. Do you recognize those e-mails?</p> <p>3 A. I don't remember them, no.</p> <p>4 Q. Okay. Who is Kenneth Yamashita?</p> <p>5 A. He was a site director at the time.</p> <p>6 Q. Okay. In your June 20th e-mail you 7 say "I briefed Clay on the situation on your 8 absence."</p> <p>9 Who was Clay?</p> <p>10 A. Clay Wagner was the plant controller, 11 so he was the designee when Ken Yamashita was 12 out of the office.</p> <p>13 Q. The last sentence of that paragraph 14 says "We have been asked to provide information 15 on our Suspicious Order Monitoring Program and 16 how it relates to quota and ties in with 17 St. Louis plant manufacturing quota."</p> <p>18 What was that information? How did 19 the SOM program relate to quota and tie in with 20 the St. Louis plant manufacturing quota?</p> <p>21 MR. O'CONNOR: Objection to form.</p> <p>22 A. So we explained to DEA, we hosted them 23 on-site, and we explained to them the quota 24 process at a high level, because DI White was</p>	<p>1 Q. Okay. So Mr. Yamashita then responds 2 to you "Great. Thanks for the update. Did you 3 get the impression now that if our quota 4 justification and suspicious order monitoring 5 program is good, we will get the quota or at 6 least some portion?"</p> <p>7 Do you remember what your answer to 8 that was?</p> <p>9 A. No.</p> <p>10 Q. So Mr. Yamashita seems to be at least 11 questioning whether -- or inquiring into whether 12 the quality of the suspicious order monitoring 13 program could have an effect on the DEA's 14 decision as to quota to grant, is that how you 15 understand his e-mail?</p> <p>16 MR. O'CONNOR: Objection to form.</p> <p>17 A. I don't know what his thoughts were at 18 that time.</p> <p>19 BY MR. GOTTO:</p> <p>20 Q. Okay. Was it your belief at this 21 time, or has it been at any time, that the DEA 22 would be more likely to grant a quota request if 23 it were persuaded that the suspicious order 24 monitoring program was of high quality?</p>

Page 246	Page 248
<p>1 A. No. Ken Yamashita was new to the 2 plant at that time, he was probably just 3 learning about how it works and what the 4 expectations are.</p> <p>5 Q. Okay.</p> <p>6 (Whereupon, Mallinckrodt-Spaulding-35 7 was marked for identification.)</p> <p>8 BY MR. GOTTO:</p> <p>9 Q. Exhibit 35 is a multi-page e-mail 10 thread, MNK-T1_0000283719. These are e-mails 11 from 2011 regarding quota requests. If you'd 12 take a look at them for just a moment, please. 13 My particular question is on the e-mail that's 14 on the second page.</p> <p>15 (Witness reviewing document.)</p> <p>16 A. Okay.</p> <p>17 Q. Do you recognize these e-mails?</p> <p>18 A. Vaguely.</p> <p>19 Q. Okay. So the e-mail at the bottom of 20 the first page onto the second page, is that 21 from Frank Sapienza?</p> <p>22 A. No, so that's the bottom -- I'm sorry, 23 bottom e-mail of the first page?</p> <p>24 Q. Yes, the one that starts "Hi Karen."</p>	<p>1 Q. Do you know if it's a group at the 2 DEA?</p> <p>3 A. I don't.</p> <p>4 (Whereupon, Mallinckrodt-Spaulding-36 5 was marked for identification.)</p> <p>6 BY MR. GOTTO:</p> <p>7 Q. Exhibit 36 is a two-page document 8 beginning at Bates MNK-T1_0006055924. It 9 appears to be an e-mail exchange in August of 10 2012 concerning safety stock. Tell me if you 11 recognize those e-mails, please.</p> <p>12 (Witness reviewing document.)</p> <p>13 A. Okay.</p> <p>14 Q. Do you recognize those e-mails?</p> <p>15 A. No.</p> <p>16 Q. Okay. There is -- the e-mail in the 17 middle of the first page from you to Kevin 18 Hewlett -- first of all, who is Kevin Hewlett?</p> <p>19 A. He was the corporate planning manager 20 at the time.</p> <p>21 Q. Okay. You make reference to a formula 22 that was used in favor of the most recent 23 several requests. Is the formula the formula 24 that's in the attachment?</p>
<p style="text-align: center;">Page 247</p> <p>1 A. Yes. What we referred to earlier in 2 which they have to go for additional signatures.</p> <p>3 Q. Okay. And then on the second page, 4 the material in the middle that starts with "One 5 of our industry colleagues forwarded" --</p> <p>6 A. Yes.</p> <p>7 Q. -- who is it that was sending that 8 e-mail?</p> <p>9 A. I have no idea. Oh, sending it, 10 that's Karen.</p> <p>11 Q. Okay. And so this is information that 12 Ms. Harper received from someone else in the 13 industry in June of 2011, correct?</p> <p>14 A. That's my understanding of this, yes.</p> <p>15 Q. Okay. And so in this -- on these 16 eight points, the fifth point is "External 17 review 3: The suspicious order monitoring group 18 reviews and makes sure our material is not being 19 used to complete suspicious orders."</p> <p>20 Do you have an understanding as to who 21 the suspicious order monitoring group is that's 22 referred to in that item?</p> <p>23 A. No, because this is pulled from 24 somebody else in industry.</p>	<p style="text-align: center;">Page 249</p> <p>1 A. Yes.</p> <p>2 Q. And is this what you discussed -- you 3 testified to, I think this morning, regarding 4 quota formula?</p> <p>5 A. Yes.</p> <p>6 Q. So this was the formula that was used 7 back in 2012?</p> <p>8 A. Yes.</p> <p>9 Q. Has the formula changed since that 10 time?</p> <p>11 A. No.</p> <p>12 Q. Okay. You can set that aside.</p> <p>13 (Whereupon, Mallinckrodt-Spaulding-37 14 was marked for identification.)</p> <p>15 BY MR. GOTTO:</p> <p>16 Q. Exhibit 37 is a one-page e-mail, 17 MNK-T1_0006056192. This appears to also be the 18 quota formula. Could you take a look at that 19 and confirm that for me?</p> <p>20 A. Yes. Correct.</p> <p>21 Q. Okay. You can set that aside.</p> <p>22 (Whereupon, Mallinckrodt-Spaulding-38 23 was marked for identification.)</p> <p>24 BY MR. GOTTO:</p>

Page 250	Page 252
<p>1 Q. Exhibit 38 is a multi-page e-mail 2 thread, MNK-T1_0005641401. Again, these are 3 e-mails concerning quota. And my questions for 4 you concern Ms. Johnson's e-mail at the bottom 5 of the first page.</p> <p>6 A. Okay.</p> <p>7 Q. She says "Yes, you have it straight. 8 Part of the difference is the formulas are in AA 9 and the quota analysis is in Salt."</p> <p>10 What does that mean, AA and salt in 11 this context?</p> <p>12 A. So AA is anhydrous alkaloid, and 13 that's how quota is measured by, the base 14 content. So our analysis, because we receive 15 API in its salt form isomer on the dock, our 16 analysis and what we track is all in salt form. 17 But when we have to request quota from the DEA, 18 we have to convert it back to AA, and every 19 molecule has its own conversion factor to go 20 from salt to AA.</p> <p>21 Q. Okay. You can set that aside.</p> <p>22 (Whereupon, Mallinckrodt-Spaulding-39 23 was marked for identification.)</p> <p>24 BY MR. GOTTO:</p>	<p>1 And with respect to Exhibit 39, we are 2 now making a clawback request with respect to 3 that because this document is protected by the 4 attorney/client privilege as well as the work 5 product protection, and we'll be following up 6 with a letter shortly.</p> <p>7 MR. GOTTO: Okay. And as to 39, 8 that's the entire document?</p> <p>9 MR. O'CONNOR: That's correct.</p> <p>10 MR. GOTTO: Okay. Fair enough.</p> <p>11 BY MR. GOTTO:</p> <p>12 Q. Ms. Spaulding, if you'd take the 13 redacted Exhibit 33 that you now have in front 14 of you, I do have a couple questions for you on 15 that. And this is Bates MNK-T1_0000290887. 16 Take a look -- it's a one-page e-mail thread. 17 Take a look at that, if you would, and tell me 18 if you recognize it.</p> <p>19 A. Yes.</p> <p>20 Q. And so your e-mail to Mr. Nikolaus on 21 January 14 of 2011 indicates that you "just got 22 off a Suspicious Order Monitoring Steering 23 Committee conference call discussing the SOM 24 audits. I sent Karen the preliminary report</p>
Page 251	Page 253
<p>1 Q. Exhibit 39 is a two-page e-mail 2 beginning at Bates MNK-T1_0007729523, appears to 3 be an e-mail that you sent to Donald Lohman, 4 L-O-H-M-A-N.</p> <p>5 Who is Mr. Lohman?</p> <p>6 A. He's our legal counsel.</p> <p>7 Q. Okay.</p> <p>8 MR. O'CONNOR: Counsel, maybe now is a 9 good time for a break.</p> <p>10 MR. GOTTO: Sounds like it might be.</p> <p>11 THE VIDEOGRAPHER: The time is 12 3:49 p.m., and we're off the record. 13 (Whereupon, a recess was taken.)</p> <p>14 THE VIDEOGRAPHER: The time is 15 4:04 p.m., and we're on the record.</p> <p>16 MR. GOTTO: Counsel?</p> <p>17 MR. O'CONNOR: All right. Counsel, 18 thank you for that break.</p> <p>19 Just to clarify what's transpired 20 here, with respect to Exhibit 33, that document 21 was clawed back pursuant to a November 27, 2018 22 letter, so we have just gone ahead during the 23 break and replaced the unredacted, clawed back 24 version with the redacted version.</p>	<p>1 awaiting any comments from you. Basically the 2 committee has decided to release Masters and 3 KeySource to resume shipping Oxy 15-milligram 4 and 30-milligram when we come out of backorder, 5 but has determined based on our audit that 6 Cedardale does not have a robust enough system 7 in place to resume shipping C2s to them."</p> <p>8 Correct?</p> <p>9 A. Yes.</p> <p>10 Q. Do you recall that decision by the 11 committee?</p> <p>12 A. Based on this e-mail, yes.</p> <p>13 Q. So you don't have an independent 14 recollection of what the basis was for the 15 decision to release Masters and KeySource at 16 this point?</p> <p>17 A. No.</p> <p>18 Q. Okay. You can set that aside. 19 (Whereupon, Mallinckrodt-Spaulding-40 20 was marked for identification.)</p> <p>21 BY MR. GOTTO:</p> <p>22 Q. Exhibit 40 is a two-page document, 23 MNK-T1_0006442504, appears to be an e-mail from 24 you to Richard Nikolaus dated July 17th of 2008</p>

Page 254	Page 256
<p>1 attaching a letter to Denise Jordan at DEA.</p> <p>2 Take a moment and tell me if you recognize that</p> <p>3 e-mail and the attachment.</p> <p>4 A. I don't recognize the e-mail, but it</p> <p>5 is one of my letters.</p> <p>6 Q. Okay. So in your e-mail you say</p> <p>7 "Rich, Take a look when you get a chance and let</p> <p>8 me know what you think. I'm running out of BS</p> <p>9 to put in these letters, especially this one."</p> <p>10 And then the letter is to Denise</p> <p>11 Jordan at the DEA.</p> <p>12 Who was Denise Jordan?</p> <p>13 A. She was the diversion investigator</p> <p>14 responsible for our site at that time.</p> <p>15 Q. And so your letter is in response to</p> <p>16 an inquiry you received from her, is that right?</p> <p>17 A. No, this is attached filing a 106. So</p> <p>18 we had a loss in transit, and this is</p> <p>19 notification to DEA of the details regarding the</p> <p>20 loss in transit.</p> <p>21 Q. Okay. So judging from your cover</p> <p>22 e-mail where you say "I'm running out of BS to</p> <p>23 put in these letters," was there something in</p> <p>24 the Denise Jordan letter that you were referring</p>	<p>1 (Whereupon, Mallinckrodt-Spaulding-41</p> <p>2 was marked for identification.)</p> <p>3 BY MR. GOTTO:</p> <p>4 Q. Exhibit 41 is a copy of the</p> <p>5 Administrative Memorandum of Agreement between</p> <p>6 Mallinckrodt and the DEA from 2017. Take a look</p> <p>7 at that document, if you would. First tell me</p> <p>8 if you've seen it before.</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Are you familiar with it?</p> <p>11 A. Yes.</p> <p>12 Q. When did you first become aware that</p> <p>13 the DEA was formally investigating Mallinckrodt?</p> <p>14 A. During the 2013 inspection.</p> <p>15 Q. Okay. Did you receive copies of</p> <p>16 subpoenas that were issued by DEA in 2011 and</p> <p>17 2012?</p> <p>18 A. I've received copies of subpoenas. I</p> <p>19 don't remember if they were 2011 or 2012.</p> <p>20 Q. Okay. But you recall in 2013 becoming</p> <p>21 aware of the investigation?</p> <p>22 A. Yes, because of the audit that was</p> <p>23 conducted in March and April of 2013.</p> <p>24 Q. Okay. And what was it about that</p>
Page 255	Page 257
<p>1 to in particular by that phrase?</p> <p>2 A. No, I was -- it was a poor choice of</p> <p>3 words basically. I was running out of</p> <p>4 explanations to explain why FedEx had lost</p> <p>5 another package.</p> <p>6 Q. And is that because there had been a</p> <p>7 large number of incidents like that?</p> <p>8 A. I don't know how many there had been</p> <p>9 during this specific time frame.</p> <p>10 Q. So were there other communications --</p> <p>11 when you say "to put in these letters," by</p> <p>12 "these letters" you mean letters to the DEA</p> <p>13 dealing with a loss incident?</p> <p>14 A. Yes. Because FedEx would give us very</p> <p>15 little information, so we were, you know, trying</p> <p>16 to be factual in what we put to DEA, but DEA</p> <p>17 would sometimes push back and say, well, what is</p> <p>18 FedEx doing about it? And we'd go to FedEx and</p> <p>19 say, what are you doing about it? And they'd</p> <p>20 say, that's an internal investigation, we can't</p> <p>21 disclose an internal investigation, we can't</p> <p>22 disclose an internal investigation. So as -- we</p> <p>23 were caught between a rock and a hard place.</p> <p>24 Q. Okay. You can put that aside.</p>	<p>1 audit that made you become aware of the</p> <p>2 investigation?</p> <p>3 A. They had 15 to 16 agents and were</p> <p>4 there for 6 weeks, which was unprecedented to</p> <p>5 any other audit that had ever been done previous</p> <p>6 to that.</p> <p>7 Q. So in previous audits, approximately</p> <p>8 how many people would be there and for</p> <p>9 approximately how long?</p> <p>10 A. Two to four days and less than a</p> <p>11 week -- sorry. Two to four people, and there</p> <p>12 less than a week.</p> <p>13 Q. Okay. Did you provide any sworn</p> <p>14 testimony to DEA as part of your investigation?</p> <p>15 A. Sworn testimony, no, I don't believe</p> <p>16 so.</p> <p>17 Q. Okay. No affidavits, anything like</p> <p>18 that?</p> <p>19 A. There was an inspection report that</p> <p>20 was signed. There was legal documents provided.</p> <p>21 But I don't recall signing anything.</p> <p>22 Q. Okay. You do recall receiving a</p> <p>23 subpoena from the DEA at some point, correct?</p> <p>24 A. Yes, I received them frequently for</p>

Page 258	Page 260
<p>1 shipping verifications.</p> <p>2 Q. Okay. And do you recall receiving a</p> <p>3 subpoena that you understood to be in connection</p> <p>4 with the DEA's investigation of Mallinckrodt?</p> <p>5 A. No.</p> <p>6 Q. Were you aware of anyone else at</p> <p>7 Mallinckrodt giving a deposition or sworn</p> <p>8 statement to the DEA in connection with its</p> <p>9 investigation of Mallinckrodt?</p> <p>10 A. Not that I was aware of, no.</p> <p>11 Q. Did you have any involvement in the</p> <p>12 discussions between Mallinckrodt and DEA that</p> <p>13 led up to the memorandum of agreement?</p> <p>14 A. Yes.</p> <p>15 Q. What discussions were you involved in?</p> <p>16 A. So we were -- we went to Albany DEA</p> <p>17 and met with them to review the mass balance</p> <p>18 records after they had taken copies of all of</p> <p>19 the batch records that were part of the audit.</p> <p>20 There was follow-up questions from DEA regarding</p> <p>21 the reports that we had provided, so those were</p> <p>22 all answered. That was my direct involvement</p> <p>23 with DEA.</p> <p>24 Q. What are the mass balance records?</p>	<p>1 Hobart site making sure that anything we agreed</p> <p>2 to was feasible to manage and manageable.</p> <p>3 Q. Okay. On the first page of the</p> <p>4 administrative memorandum of agreement, there</p> <p>5 are a number of numbered paragraphs under</p> <p>6 "Background."</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And do you recall reviewing those</p> <p>10 paragraphs when you reviewed a draft of this</p> <p>11 document?</p> <p>12 A. Yes.</p> <p>13 Q. And was there any inaccuracy in any of</p> <p>14 those paragraphs that you can recall from your</p> <p>15 review?</p> <p>16 A. Not that I recall.</p> <p>17 Q. In Paragraph 2 it indicates that "From</p> <p>18 January 1, 2008, through September 30, 2011,</p> <p>19 there was an epidemic increase in diversion of</p> <p>20 the controlled substance oxycodone, largely out</p> <p>21 of the State of Florida."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. Was that a circumstance you were aware</p>
<p style="text-align: center;">Page 259</p> <p>1 A. So that's how DEA does an audit of a</p> <p>2 manufacturer. They basically take your</p> <p>3 year-ending inventory, add in all your</p> <p>4 acquisitions, and subtract out all your</p> <p>5 dispositions.</p> <p>6 Q. And the review that you participated</p> <p>7 in with the Albany DEA, what was the focus of</p> <p>8 that review?</p> <p>9 A. They audit three major molecules and</p> <p>10 all products produced within 14 months of</p> <p>11 oxycodone, hydrocodone, and Methadone.</p> <p>12 Q. Did that review disclose any</p> <p>13 discrepancies?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. I don't know. DEA never provides us</p> <p>16 reports, so I don't know what they came up with.</p> <p>17 BY MR. GOTTO:</p> <p>18 Q. Did you review a draft of the</p> <p>19 administrative memorandum of agreement before it</p> <p>20 was signed?</p> <p>21 A. Yes.</p> <p>22 Q. And what was the purpose of your</p> <p>23 review?</p> <p>24 A. Because I was the key person at the</p>	<p style="text-align: center;">Page 261</p> <p>1 of during the time period January 1 of '08</p> <p>2 through September 30th of 2011?</p> <p>3 A. I don't know if I was aware of it at</p> <p>4 that time or not.</p> <p>5 Q. Paragraph 3 indicates that "The United</p> <p>6 States alleges that Mallinckrodt, a manufacturer</p> <p>7 and distributor of oxycodone, knew about the</p> <p>8 diversion and sold excessive amounts of the most</p> <p>9 highly abused forms of oxycodone, 30-milligram</p> <p>10 and 15-milligram tablets, placing them into a</p> <p>11 stream of commerce that would result in</p> <p>12 diversion."</p> <p>13 Did you believe that that allegation</p> <p>14 was accurate when you reviewed a draft of this</p> <p>15 document?</p> <p>16 A. No.</p> <p>17 Q. What parts of it do you think were</p> <p>18 inaccurate?</p> <p>19 A. That we knowingly sold excessive</p> <p>20 amounts.</p> <p>21 Q. Okay. Paragraph 4 indicates that</p> <p>22 "Mallinckrodt had a responsibility to maintain</p> <p>23 effective controls against diversion, including</p> <p>24 a requirement that it review and monitor these</p>

Page 262	Page 264
<p>1 sales and report suspicious orders to DEA."</p> <p>2 Did you believe that was accurate when</p> <p>3 you reviewed it?</p> <p>4 A. Yes.</p> <p>5 Q. Paragraph 5, the last sentence states</p> <p>6 "Furthermore, the United States alleges that</p> <p>7 Mallinckrodt never notified the DEA of the</p> <p>8 suspicious orders in violation of the CSA."</p> <p>9 Did you believe that statement was --</p> <p>10 or that that allegation was accurate when you</p> <p>11 reviewed a draft of this document?</p> <p>12 A. No.</p> <p>13 Q. If you'd turn to Paragraph 3 on Page 2</p> <p>14 of the document, Paragraph 3(a) states that</p> <p>15 "With respect to its distribution of oxycodone</p> <p>16 and hydrocodone products, Mallinckrodt's alleged</p> <p>17 failure to distribute these controlled</p> <p>18 substances in a manner authorized by its</p> <p>19 registration and Mallinckrodt's alleged failure</p> <p>20 to operate an effective suspicious order</p> <p>21 monitoring system and to report suspicious</p> <p>22 orders to the DEA when discovered as required by</p> <p>23 and in violation of 21 CFR Section 1301.74(b)."</p> <p>24 Did you believe that the allegations</p>	<p>1 conduct adequate due diligence of its customers?</p> <p>2 A. Yes.</p> <p>3 Q. And do you believe -- under Roman</p> <p>4 Numeral ii, do you believe that Mallinckrodt</p> <p>5 detected and reported to the DEA orders of</p> <p>6 unusual size and frequency?</p> <p>7 A. What is an order of unusual size and</p> <p>8 frequency? I mean, yes, we did the best with</p> <p>9 the information we had.</p> <p>10 Q. You understood that there was a</p> <p>11 regulatory obligation to report orders of</p> <p>12 unusual size and frequency, correct?</p> <p>13 A. Yes.</p> <p>14 Q. The next paragraph, "detect and report</p> <p>15 to the DEA orders deviating substantially from</p> <p>16 normal patterns."</p> <p>17 Again, you understood that there was a</p> <p>18 regulatory requirement to detect and report such</p> <p>19 orders, correct?</p> <p>20 A. Yes.</p> <p>21 Q. And do you believe Mallinckrodt did</p> <p>22 so?</p> <p>23 A. Yes.</p> <p>24 Q. Paragraph iv, "use 'chargeback'</p>
<p style="text-align: center;">Page 263</p> <p>1 described in that sentence were accurate when</p> <p>2 you reviewed a draft of this document?</p> <p>3 A. The alleged allegations, yes.</p> <p>4 Q. You understand --</p> <p>5 A. Wait a minute. I'm sorry, I don't</p> <p>6 understand.</p> <p>7 Q. You understood it was accurate that</p> <p>8 those allegations were made. My question is,</p> <p>9 did you believe that the underlying allegations</p> <p>10 were accurate?</p> <p>11 A. No.</p> <p>12 Q. And in what regard did you believe</p> <p>13 they were not accurate?</p> <p>14 A. We were reporting any orders that we</p> <p>15 deemed to be truly suspicious, and I don't</p> <p>16 believe that we failed to report any suspicious</p> <p>17 orders. And although there's allegations and we</p> <p>18 settled with the MOA, we didn't admit any</p> <p>19 wrongdoing.</p> <p>20 Q. And under paragraph A, there's</p> <p>21 specific -- in the Roman Numeral numbered</p> <p>22 paragraphs, number "i. conduct adequate due</p> <p>23 diligence of its customers."</p> <p>24 Do you believe that Mallinckrodt did</p>	<p style="text-align: center;">Page 265</p> <p>1 information from its distributors to evaluate</p> <p>2 suspicious orders."</p> <p>3 Prior to October of 2010, Mallinckrodt</p> <p>4 did not use chargeback data as part of its SOM</p> <p>5 program, correct?</p> <p>6 A. No, it's not part of the regulations.</p> <p>7 Q. And Roman Numeral v, "take sufficient</p> <p>8 action to prevent recurrence of diversion by</p> <p>9 downstream customers after receiving concrete</p> <p>10 information of diversion of Mallinckrodt product</p> <p>11 by those downstream customers."</p> <p>12 Do you believe that Mallinckrodt was</p> <p>13 under an obligation to take action to prevent</p> <p>14 recurrence of diversion in these circumstances?</p> <p>15 MR. O'CONNOR: Objection to form.</p> <p>16 A. Not under the regulations, but as part</p> <p>17 of our MOA, yes.</p> <p>18 BY MR. GOTTO:</p> <p>19 Q. Paragraph B has a series of</p> <p>20 allegations regarding the Hobart facility,</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. And these are matters that you have</p> <p>24 some personal familiarity with, correct?</p>

Page 266	Page 268
<p>1 A. Yes.</p> <p>2 Q. And so paragraph "i. failure to take</p> <p>3 actual weights of controlled substances at all</p> <p>4 stages of the manufacturing process."</p> <p>5 Did you feel that was an accurate</p> <p>6 allegation?</p> <p>7 A. Yes.</p> <p>8 Q. And what was done to rectify that</p> <p>9 situation going forward?</p> <p>10 A. We immediately at the -- this was</p> <p>11 discovered during the 2013 audit, and so we</p> <p>12 immediately updated the records that didn't have</p> <p>13 complete weights, complete physical inventory of</p> <p>14 the entire site was taken to make sure we had a</p> <p>15 complete and accurate inventory, and we changed</p> <p>16 our receiving process to do a check-weigh on all</p> <p>17 API coming in, not just a seal verification and</p> <p>18 label verification.</p> <p>19 Q. Okay. Paragraph ii, Roman ii, "use of</p> <p>20 a 'target' tablet weight for purposes of</p> <p>21 reconciling batch records and determining the</p> <p>22 number of units of finished form manufactured</p> <p>23 even though the actual average weight of the</p> <p>24 tablets in any specific batch sometimes deviated</p>	<p>1 A. Because of the way that the dust</p> <p>2 collectors operate and are designed, there is</p> <p>3 challenges with being able to account for any</p> <p>4 specific batch, but it's not a result of not</p> <p>5 trying to determine how much went into each</p> <p>6 batch.</p> <p>7 BY MR. GOTTO:</p> <p>8 Q. How about Roman Number iv, "failure to</p> <p>9 check-weigh controlled substances received into</p> <p>10 the facility," was that an accurate allegation?</p> <p>11 A. Yes.</p> <p>12 Q. What was done to rectify that?</p> <p>13 A. As mentioned before, the check-weigh</p> <p>14 of all procedures -- of all controlled</p> <p>15 substances coming into the facility.</p> <p>16 Q. And Roman Numeral v, "failure to</p> <p>17 maintain accurate records of substances</p> <p>18 transferred from the manufacturing process to</p> <p>19 Mallinckrodt's analytical laboratories," did you</p> <p>20 think that was an accurate allegation?</p> <p>21 A. Yes.</p> <p>22 Q. And what was done to rectify that?</p> <p>23 A. So there was a gap in our record</p> <p>24 receiving documents within the laboratories, and</p>
Page 267	Page 269
<p>1 from the target weight."</p> <p>2 Did you believe the allegation</p> <p>3 described in B(ii) was an accurate allegation?</p> <p>4 A. Yes.</p> <p>5 Q. And what was done to rectify that</p> <p>6 going forward?</p> <p>7 A. Again, immediately during the 2013</p> <p>8 audit before this MOA, we changed our procedures</p> <p>9 to calculate an actual weight per lot for each</p> <p>10 batch produced, and that actual weight per batch</p> <p>11 is now what's used in reconciliation purposes.</p> <p>12 Q. Okay. And B(iii) related to</p> <p>13 "commingling of dust collector waste and</p> <p>14 assignment of dust losses."</p> <p>15 Did you feel that was an accurate</p> <p>16 allegation when it was made?</p> <p>17 A. No.</p> <p>18 Q. What part of it did you think was not</p> <p>19 accurate?</p> <p>20 A. Without confirming how much dust was</p> <p>21 actually attributable to any specific batch.</p> <p>22 Q. Do you know why the DEA alleged that</p> <p>23 lack of confirmation?</p> <p>24 MR. O'CONNOR: Objection to form.</p>	<p>1 again during the 2013 audit, it was -- DEA had</p> <p>2 detected that, and we immediately updated our</p> <p>3 documents to have traceability of all samples</p> <p>4 coming into the lab regardless of their</p> <p>5 controlled substance schedule.</p> <p>6 Q. Okay. And Roman Numeral vi, "failure</p> <p>7 to include substances held in certain</p> <p>8 vaults/storage as part of the biannual</p> <p>9 inventory, and records provided for vaults</p> <p>10 containing discrepancies with respect to weight,</p> <p>11 missing substances, incorrect lots/batch</p> <p>12 numbers, and incorrect or incomplete drug</p> <p>13 names." Did you believe that was an accurate</p> <p>14 allegation when it was made?</p> <p>15 A. Yes.</p> <p>16 Q. And what was done to rectify that?</p> <p>17 A. That was part of the complete physical</p> <p>18 inventory that was taken that same time period</p> <p>19 of counting and documenting every single</p> <p>20 controlled substance in the facility.</p> <p>21 Q. So the various allegations under</p> <p>22 paragraph B that you've indicated you believed</p> <p>23 were accurate allegations when they were made,</p> <p>24 were those circumstances that came into</p>

Page 270	Page 272
<p>1 existence during 2013?</p> <p>2 A. Came, like had just started?</p> <p>3 Q. Yes.</p> <p>4 A. No.</p> <p>5 Q. Okay. Do you have any idea when they</p> <p>6 did start?</p> <p>7 A. No, that's just when they were</p> <p>8 detected.</p> <p>9 Q. And what caused them to be detected?</p> <p>10 A. Part of the audit that the DEA</p> <p>11 conducted.</p> <p>12 Q. And do you know what was different in</p> <p>13 the 2013 audit that gave rise to that detection</p> <p>14 that hadn't caused these circumstances to be</p> <p>15 detected previously?</p> <p>16 A. In the 2000 DEA -- 2013 DEA audit,</p> <p>17 there was more investigators there, and they</p> <p>18 were going through the batch records in greater</p> <p>19 detail than they had in any previous audit.</p> <p>20 Q. Okay. Paragraph 4 states it is not an</p> <p>21 admission of liability, however, Mallinckrodt</p> <p>22 agrees that at certain times certain aspects of</p> <p>23 Mallinckrodt's system to monitor and detect</p> <p>24 suspicious orders did not meet the standards</p>	<p>1 given.</p> <p>2 Q. Did you ever receive any performance</p> <p>3 evaluation that -- well, strike that.</p> <p>4 In any of your performance evaluations</p> <p>5 that you received at Mallinckrodt, was the</p> <p>6 subject of the suspicious order monitoring</p> <p>7 program one of the items on which you were</p> <p>8 evaluated?</p> <p>9 A. Yes.</p> <p>10 Q. And what evaluations did you receive</p> <p>11 in that regard?</p> <p>12 A. I was always meeting expectations.</p> <p>13 Q. And who was it who performed your</p> <p>14 evaluations?</p> <p>15 A. My manager.</p> <p>16 Q. Ms. Harper?</p> <p>17 A. Yes.</p> <p>18 Q. You were familiar with the DEA letters</p> <p>19 from September of '06 and December of '07 that</p> <p>20 are referred to in Paragraph 4, correct?</p> <p>21 A. Yes.</p> <p>22 Q. So if, in fact, aspects of</p> <p>23 Mallinckrodt's SOM program did not meet the</p> <p>24 standards outlined in those letters, that</p>
<p>1 outlined in letters from the DEA deputy</p> <p>2 administrator from September and December of</p> <p>3 2006 and 2007 respectively.</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. And do you believe that's true, that</p> <p>7 certain aspects of the SOM program in place at</p> <p>8 Mallinckrodt prior to January 1, 2012 did not</p> <p>9 meet standards outlined in those letters?</p> <p>10 A. Do I personally?</p> <p>11 Q. Yes.</p> <p>12 A. No, I believe they did.</p> <p>13 Q. Do you know why Mallinckrodt agreed</p> <p>14 that the SOM did not meet certain of those</p> <p>15 standards?</p> <p>16 A. I do not.</p> <p>17 Q. Did you have any discussions with</p> <p>18 anyone at Mallinckrodt prior to the time this</p> <p>19 memorandum of agreement was executed with</p> <p>20 respect to that point?</p> <p>21 A. I remember having discussions. I</p> <p>22 don't know if it was part of the memorandum of</p> <p>23 agreement that we were doing the best we could</p> <p>24 with what we had and the direction we had been</p>	<p>1 failure would have indicated, at least to some</p> <p>2 extent, a personal failure on your regard -- on</p> <p>3 your part with respect to the SOM program,</p> <p>4 right?</p> <p>5 MR. O'CONNOR: Objection to form.</p> <p>6 A. I don't think I understand. Are you</p> <p>7 saying that because we admitted that our program</p> <p>8 wasn't robust I wasn't doing my job?</p> <p>9 BY MR. GOTTO:</p> <p>10 Q. Well, let me put it a little</p> <p>11 differently.</p> <p>12 During the period prior to January 1</p> <p>13 of 2012, did you attempt to cause the SOM</p> <p>14 program at Mallinckrodt to be in compliance with</p> <p>15 the standards outlined in the DEA letters of</p> <p>16 September of '06 and December of '07?</p> <p>17 A. I believe I did, yes.</p> <p>18 Q. Okay. And so if, in fact, the program</p> <p>19 was not in compliance with those standards, then</p> <p>20 that would have meant that you failed to achieve</p> <p>21 your objective in that regard, correct?</p> <p>22 MR. O'CONNOR: Objection to form.</p> <p>23 A. I disagree with that.</p> <p>24 BY MR. GOTTO:</p>

Page 274	Page 276
<p>1 Q. You disagree with whether the program 2 met the standards, right?</p> <p>3 A. No, I disagree with whether I was 4 doing what was expected of me and met the intent 5 of the letters based on the information and the 6 direction that we have. DEA gives very little 7 guidance around what is an unusual order, what 8 is a suspicious order, so we have to interpret 9 that the best that we can, and I feel that I've 10 done that.</p> <p>11 MR. GOTTO: Okay. Why don't we go off 12 the record.</p> <p>13 THE VIDEOGRAPHER: The time is 14 4:34 p.m., and we're off the record.</p> <p>15 (Whereupon, a recess was taken.)</p> <p>16 THE VIDEOGRAPHER: The time is 17 4:45 p.m., and we're on the record.</p> <p>18 EXAMINATION</p> <p>19 BY MR. GESTEL:</p> <p>20 Q. Good evening, Ms. Spaulding.</p> <p>21 MR. GESTEL: Before I begin, I'll just 22 launch what has become our standard objection 23 without going into the whole basis for that, if 24 you'll let me. I assume that you'll --</p>	<p>1 any time soon?</p> <p>2 A. Not that I foresee.</p> <p>3 Q. And then, if this was covered this</p> <p>4 morning I apologize, but can you do a -- provide 5 some -- a little bit of your educational 6 background?</p> <p>7 Did you graduate from college?</p> <p>8 A. Again, I have an associate from BYU in 9 computer information systems.</p> <p>10 Q. When you say BYU, is that Brigham and 11 Young University?</p> <p>12 A. Yes, the Idaho campus.</p> <p>13 Q. And how long ago did you receive that 14 degree?</p> <p>15 A. 1990.</p> <p>16 Q. And were you living in Idaho at the 17 time?</p> <p>18 A. While I attended college. No, I lived 19 in New Jersey, went to college in Idaho, and 20 came back to New Jersey.</p> <p>21 Q. Got it. Thank you very much.</p> <p>22 And what is your current title at 23 Mallinckrodt?</p> <p>24 A. Controlled substances compliance</p>
<p>1 MR. O'CONNOR: I'll offer our standard 2 objection to the objection.</p> <p>3 MR. GESTEL: All right. Thank you.</p> <p>4 BY MR. GESTEL:</p> <p>5 Q. Ms. Spaulding, my name is Ben Gestel. 6 I represent a group of plaintiffs in the State 7 of Tennessee that are in a slightly different 8 lawsuit than the lawsuit that Mr. Gotto was 9 asking you questions about this morning.</p> <p>10 I'll begin by asking you, have you 11 reviewed the complaint in any of the Tennessee 12 cases?</p> <p>13 A. No.</p> <p>14 Q. I'm going to also sort of back up and 15 do a couple of preliminary things.</p> <p>16 Where do you live? What is your 17 residential address?</p> <p>18 A. [REDACTED]</p> <p>20 Q. And how long have you lived there?</p> <p>21 A. 12 years.</p> <p>22 Q. And who lives there with you?</p> <p>23 A. Currently alone.</p> <p>24 Q. And then do you have any plans to move</p>	<p>1 manager.</p> <p>2 Q. And in that role do you have 3 supervisory authority over any employees?</p> <p>4 A. Yes, I have two employees on my team.</p> <p>5 Q. Who is directly reporting to you?</p> <p>6 A. Carrie Johnson and Rachelle Rogers.</p> <p>7 Q. And if I'm understanding the testimony 8 earlier, are you continuing to directly report 9 to Karen Harper?</p> <p>10 A. I am.</p> <p>11 Q. In your work with Mallinckrodt, did 12 you have occasion to travel to the State of 13 Tennessee?</p> <p>14 A. I have attended a conference in 15 Tennessee.</p> <p>16 Q. Do you remember what conference that 17 was?</p> <p>18 A. NADDI conference in Nashville.</p> <p>19 Q. Do you remember what year that was?</p> <p>20 A. Not the exact. It's within the past 21 five years.</p> <p>22 Q. Apart from attending that NADDI 23 conference in Nashville, do you recall ever 24 travelling to the State of Tennessee for your</p>

Page 278	Page 280
<p>1 work for Mallinckrodt?</p> <p>2 A. No.</p> <p>3 Q. So you don't ever recall travelling to</p> <p>4 a distributor's facility in Tennessee to do an</p> <p>5 audit?</p> <p>6 A. I stand corrected. I have travelled</p> <p>7 to Memphis in my role at Mallinckrodt to FedEx.</p> <p>8 And I've been to a distributor -- no, they're</p> <p>9 not in Tennessee, sorry. Just FedEx in Memphis,</p> <p>10 Tennessee.</p> <p>11 Q. And do you recall when it was you went</p> <p>12 to FedEx?</p> <p>13 A. Not exactly. I've been there three or</p> <p>14 four times.</p> <p>15 Q. When was the most recent trip that you</p> <p>16 were there?</p> <p>17 A. It's been many years.</p> <p>18 Q. And can you just provide a general</p> <p>19 overview of what you were doing at that FedEx</p> <p>20 facility?</p> <p>21 A. We were doing a collaboration visit.</p> <p>22 They gave us a tour of the facility. We were</p> <p>23 conducting an audit because we had had some</p> <p>24 losses in transit with FedEx, and reviewing</p>	<p>1 BY MR. GESTEL:</p> <p>2 Q. And are you aware that epidemic is</p> <p>3 particularly acute in some parts of the country</p> <p>4 compared to other parts of the country?</p> <p>5 MR. O'CONNOR: Objection to form.</p> <p>6 A. Yes.</p> <p>7 BY MR. GESTEL:</p> <p>8 Q. Do you believe that Tennessee has been</p> <p>9 particularly hard-hit by the opioid crisis?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. I don't know how significant or hit</p> <p>12 any one state is over another.</p> <p>13 BY MR. GESTEL:</p> <p>14 Q. Sure.</p> <p>15 But do you understand or do you</p> <p>16 believe that Tennessee has -- is one part of</p> <p>17 those country -- one part of this country that</p> <p>18 has been particularly hit by the opioid</p> <p>19 epidemic?</p> <p>20 MR. O'CONNOR: Objection.</p> <p>21 A. I'm aware that Tennessee has concerns.</p> <p>22 I don't know the specific facts to know whether</p> <p>23 it was one of the highest or not or more so than</p> <p>24 any other state.</p>
<p style="text-align: center;">Page 279</p> <p>1 their security procedures and how they handle</p> <p>2 Mallinckrodt freight when it goes through the</p> <p>3 hub.</p> <p>4 Q. And was this before the transition</p> <p>5 over to the FedEx Express service that you</p> <p>6 talked about this morning?</p> <p>7 A. It was after.</p> <p>8 Q. It was after that.</p> <p>9 And you said "we went." Do you recall</p> <p>10 who went with you?</p> <p>11 A. Security managers, Rich Nikolaus.</p> <p>12 Q. Anybody else attend on that trip?</p> <p>13 A. No, not that I can recall.</p> <p>14 Q. As you sit there today, do you have</p> <p>15 any understanding of opioid prescription rates</p> <p>16 in the State of Tennessee?</p> <p>17 A. No.</p> <p>18 MR. O'CONNOR: Objection to form.</p> <p>19 BY MR. GESTEL:</p> <p>20 Q. I think you testified earlier that you</p> <p>21 believe that there's a current opioid epidemic</p> <p>22 going on in this country, is that correct?</p> <p>23 MR. O'CONNOR: Objection.</p> <p>24 A. I'm aware of it.</p>	<p style="text-align: center;">Page 281</p> <p>1 BY MR. GESTEL:</p> <p>2 Q. Do you recall during your time with</p> <p>3 Mallinckrodt ever discussing any specific pill</p> <p>4 mill operations in the State of Tennessee?</p> <p>5 MR. O'CONNOR: Objection to form.</p> <p>6 A. Nothing specific, no.</p> <p>7 BY MR. GESTEL:</p> <p>8 Q. Have you ever reviewed IMS Health data</p> <p>9 regarding the rates of prescribing of opioids</p> <p>10 related to the State of Tennessee?</p> <p>11 A. No.</p> <p>12 Q. Have you ever heard of Interstate 75</p> <p>13 being described as the "Oxy Express"?</p> <p>14 A. Yes.</p> <p>15 Q. About when did you first hear that</p> <p>16 term?</p> <p>17 A. Several years ago. I don't remember</p> <p>18 exactly when.</p> <p>19 Q. And I don't mean to test your</p> <p>20 knowledge of American geography, but are you</p> <p>21 aware that Interstate 75 runs through the State</p> <p>22 of Tennessee?</p> <p>23 A. At a high level, yes.</p> <p>24 Q. In your role as manager of controlled</p>

Page 282	Page 284
<p>1 substances, did you interact with law 2 enforcement officials in the State of Tennessee? 3 A. I interact with law enforcement 4 officials. I don't remember specifically if any 5 of them have been from Tennessee. They could 6 have, but I don't know specifically. 7 Q. Did you have occasion to ever just 8 have a conversation with a police officer from 9 Morristown, Tennessee? Does that ring a bell in 10 your mind at all? 11 A. I believe the security director had a 12 conversation with someone from Morristown, 13 Morrisville. 14 Q. But you weren't involved in that 15 conversation, to the best of your recollection? 16 A. No, not directly. 17 Q. How did you learn about it indirectly? 18 A. The security director asked me for 19 shipping information, that he had been contacted 20 by somebody from Morrisville, Tennessee. 21 Q. And then why would he contact you 22 about that information, if you know? 23 A. Because I was at the distribution 24 center and could run the reports to know what --</p>	<p>1 distributors in certain states? 2 A. I have not, no. 3 Q. I'm going to hand you a document that 4 we'll mark as Exhibit 42. 5 (Whereupon, Mallinckrodt-Spaulding-42 6 was marked for identification.) 7 MR. GESTEL: (Handing). Sorry, that 8 was a little -- like Tom Brady over here. 9 BY MR. GESTEL: 10 Q. I hand you a document that's been 11 marked as Exhibit 42. I'll represent to you 12 that the first page is a cover page carrying the 13 Bates label of this Excel spreadsheet that was 14 sent to us, and it has some what's called 15 metadata showing that it was last modified on 16 September 2, 2011. The reason why we do that, 17 ma'am, is that the spreadsheet was produced to 18 us in native format so the Bates numbers don't 19 appear, but that's the Bates number of this 20 document. 21 And if you flip to the first page, in 22 the upper left-hand corner there is in column 23 A1, it says "Oxy's percent of sales by state per 24 distributor versus sales in all US by district,"</p>
Page 283	Page 285
<p>1 where we shipped our orders to. 2 Q. And then did you provide him the 3 report that he asked for? 4 A. Yes. 5 Q. And then did you follow up with him at 6 all after providing that report about the status 7 of that Morristown investigation? 8 A. No. 9 Q. Have you ever asked any law 10 enforcement official about prescription opioid 11 division -- I'm sorry, strike that. 12 Have you ever asked any law 13 enforcement official where prescription opioid 14 diversion was most prevalent? 15 A. No, not that I can recall. 16 Q. During your time with Mallinckrodt, 17 have you ever had occasion to run reports 18 detailing the percentage of oxycodone sales for 19 Mallinckrodt's distributors in certain states? 20 A. Can you say that again? 21 Q. Sure. 22 During your time with Mallinckrodt, 23 have you had occasion to run reports detailing 24 the percentage of Oxy sales for Mallinckrodt's</p>	<p>1 I assume. 2 Do you see that? 3 A. Yes. 4 Q. Have you ever seen this document 5 before, ma'am? 6 A. I don't remember if I have or have 7 not. 8 Q. Do you ever recall doing any training 9 on this document, where you might have trained 10 people to run these reports? 11 A. No. 12 Q. Do you see that the state listed here 13 is Florida? 14 A. Yes. 15 Q. And then flip to the next page. Do 16 you see that the state listed there is Texas? 17 A. Yes. 18 Q. And flip to the next page. Do you see 19 that the state listed there is Ohio? 20 A. Yes. 21 Q. And flip to the next page. Do you see 22 that the state listed there is Kentucky? 23 A. Yes. 24 Q. And then flip to the next page. And</p>

Page 286	Page 288
<p>1 do you see there that the state listed there is</p> <p>2 Tennessee?</p> <p>3 A. Yes.</p> <p>4 Q. And none of this is -- you don't</p> <p>5 believe you've ever seen this document before?</p> <p>6 A. I don't remember it.</p> <p>7 Q. And then flip to the next page. And</p> <p>8 there's the State of Georgia. Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. And then if you flip to the next page,</p> <p>11 there's a graph titled "Percent of Oxycodone</p> <p>12 Sales in Florida."</p> <p>13 Do you see that?</p> <p>14 A. Mm-hmm.</p> <p>15 Q. Do you recall ever seeing a graph like</p> <p>16 this in your work with Mallinckrodt?</p> <p>17 A. No, I don't remember.</p> <p>18 Q. And do you remember why, if at all, in</p> <p>19 2011 Mallinckrodt might have become interested</p> <p>20 in tracking oxycodone sales to the states listed</p> <p>21 in this spreadsheet?</p> <p>22 A. Only due to DEA activities around that</p> <p>23 time period.</p> <p>24 Q. And if you wanted to have a chart like</p>	<p>1 MS HOSMER: Do you have a Bates number</p> <p>2 for us, please?</p> <p>3 MR. GESTEL: Sure.</p> <p>4 MS HOSMER: Thank you.</p> <p>5 BY MR. GESTEL:</p> <p>6 Q. This is an e-mail carrying Bates label</p> <p>7 MNK-T1_0007898862. And then do you see that</p> <p>8 this is an e-mail dated November 26, 2013 from</p> <p>9 Jennifer Buist to you carrying a subject "KVK</p> <p>10 Heat Maps"? Did I read that correctly?</p> <p>11 A. Yes.</p> <p>12 Q. Do you recall this e-mail?</p> <p>13 A. Vaguely.</p> <p>14 Q. And then, let me put a clean copy up.</p> <p>15 And the first -- or the last e-mail in that</p> <p>16 chain says "These may be discussed during our</p> <p>17 staff meeting."</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. And then a couple e-mails down is an</p> <p>21 e-mail from Julie Milford to Jacob Longenecker</p> <p>22 with Jen Terp and Jennifer Buist copied.</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>
Page 287	Page 289
<p>1 this made for you, it sounds like you don't</p> <p>2 recall running these types of reports, who would</p> <p>3 you go to within Mallinckrodt in 2011, if you</p> <p>4 can recall, to run a report like this?</p> <p>5 A. Oxy sales by state by distributor. It</p> <p>6 could have been in our finance department, or it</p> <p>7 would go to our marketing department.</p> <p>8 Q. And who in those departments would you</p> <p>9 direct an inquiry to?</p> <p>10 A. Whoever was the head of the department</p> <p>11 at the time.</p> <p>12 Q. Would that have been Jen Buist?</p> <p>13 A. No. Jen Buist would have gotten it</p> <p>14 from one of those departments.</p> <p>15 Q. Would it have been Jen Terp?</p> <p>16 A. Could have been. I don't know for</p> <p>17 sure.</p> <p>18 Q. You can set that aside. Thank you</p> <p>19 very much.</p> <p>20 (Whereupon, Mallinckrodt-Spaulding-43</p> <p>21 was marked for identification.)</p> <p>22 BY MR. GESTEL:</p> <p>23 Q. I'm going to hand you a document that</p> <p>24 we'll mark as Exhibit 43.</p>	<p>1 Q. And the body of that e-mail says "Hi</p> <p>2 Jake, Attached are the heat maps with</p> <p>3 Mallinckrodt data. I also added a section on</p> <p>4 per capita usage to negate any effects or</p> <p>5 questions around population sizes. Similar</p> <p>6 patterns still exist that suggest relatively</p> <p>7 high usage in the Pacific Northwest, especially</p> <p>8 for the 5-milligram tablet. In general, there</p> <p>9 are still high rates in the KY, WV, and</p> <p>10 Tennessee area and in Florida."</p> <p>11 Did I read that correctly?</p> <p>12 A. Yes.</p> <p>13 Q. And attached to this e-mail chain is</p> <p>14 this referenced heat maps, and I think it's just</p> <p>15 a PowerPoint presentation carrying the title</p> <p>16 "Volume Heat Maps."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Do you recall ever running these heat</p> <p>20 maps while you were employed at Mallinckrodt?</p> <p>21 A. No, I didn't run them.</p> <p>22 Q. Do you recall this spread -- or this</p> <p>23 PowerPoint presentation as you sit here today?</p> <p>24 A. Now that I'm looking at it, I vaguely</p>

Page 290	Page 292
<p>1 remember it, yes.</p> <p>2 Q. And then if you flip to the first page</p> <p>3 of the PowerPoint presentation, it says "MNK</p> <p>4 geographical patterns are similar to the rest of</p> <p>5 the market."</p> <p>6 Did I read that correctly?</p> <p>7 A. You said the first page?</p> <p>8 Q. The first page of the PowerPoint.</p> <p>9 A. Yes.</p> <p>10 Q. And then there's two maps. There's a</p> <p>11 map carrying the title of "All Strengths -</p> <p>12 Mallinckrodt."</p> <p>13 Do you see that?</p> <p>14 A. "All Strengths - Mallinckrodt," yes.</p> <p>15 Q. And then the second map is "All</p> <p>16 Strengths - Other Manufacturers."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And then it appears that based on the</p> <p>20 legend here at the bottom that the deeper purple</p> <p>21 you get in an area, the more Oxy prescriptions</p> <p>22 in that area. Is that your understanding of</p> <p>23 this heat map?</p> <p>24 A. Well, it's saying "All Strengths," so</p>	<p>1 it says the source is IMS, LRx, Xponent.</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. And it's apparently from July, 2012 to</p> <p>5 June, 2013?</p> <p>6 A. Yes.</p> <p>7 Q. Do you know what the IMS, LRx, Xponent</p> <p>8 references?</p> <p>9 A. No, I do not.</p> <p>10 Q. Do you believe that that could be a</p> <p>11 reference to IMS Health data?</p> <p>12 A. Reasonably.</p> <p>13 Q. Are you familiar with IMS Health data?</p> <p>14 A. At a very, very high level.</p> <p>15 Q. Do you use that at all in suspicious</p> <p>16 order monitoring program at Mallinckrodt?</p> <p>17 A. I do not, no.</p> <p>18 Q. Do you know of anybody within the</p> <p>19 suspicious order monitoring program at</p> <p>20 Mallinckrodt who uses IMS Health data?</p> <p>21 A. Not currently, no.</p> <p>22 Q. Well, was it ever used, to the best of</p> <p>23 your knowledge?</p> <p>24 A. So I know at one point in time this</p>
<p>1 not just oxycodone.</p> <p>2 Q. Okay. But regardless, as you get more</p> <p>3 purple, you see more -- that's more units going</p> <p>4 into that geographic territory, right?</p> <p>5 A. Based on the legend.</p> <p>6 Q. And then if you look here in the area</p> <p>7 of the country that is Tennessee, you'll see</p> <p>8 that it's -- do you see that it's purple in the</p> <p>9 areas around the State of Tennessee?</p> <p>10 A. Yes, roughly.</p> <p>11 Q. And then also on the Other</p> <p>12 Manufacturers map, the State of Tennessee is</p> <p>13 kind of more purple than other areas around it.</p> <p>14 Do you see that?</p> <p>15 A. I wouldn't say it's more purple than</p> <p>16 other areas around it, but I see it.</p> <p>17 Q. But you would agree with me that</p> <p>18 that's a -- the State of Tennessee is purple in</p> <p>19 this graph, correct?</p> <p>20 A. In which one, the Other Manufacturers</p> <p>21 or the Mallinckrodt one?</p> <p>22 Q. The Other Manufacturers.</p> <p>23 A. Yes.</p> <p>24 Q. And then do you see here at the bottom</p>	<p>1 group may have had access to IMS data in which</p> <p>2 Jen Buist, who was the SOM auditor analyst at</p> <p>3 the time, may have reached out to her for</p> <p>4 information, but I don't know that and I can't</p> <p>5 speak on her behalf.</p> <p>6 Q. And when you say "this group," what do</p> <p>7 you mean?</p> <p>8 A. The commercial marketing. I don't</p> <p>9 even know who Ms. Julie Milford is, but her</p> <p>10 title says she's global business insights and</p> <p>11 forecasting, commercial analytics.</p> <p>12 Q. And you're getting that from the cover</p> <p>13 of this -- the cover e-mails?</p> <p>14 A. Yes. I don't know who she is.</p> <p>15 Q. If you'll flip back, there's a very</p> <p>16 similar map to the one we just went through</p> <p>17 carrying the labels of "30-milligram." It's</p> <p>18 about halfway back, I apologize. These</p> <p>19 PowerPoint presentations aren't numbered.</p> <p>20 There's a 30-milligram chart.</p> <p>21 A. Yes.</p> <p>22 Q. And then do you see that this</p> <p>23 particular chart carries the title "Mallinckrodt</p> <p>24 and other manufacturers have very similar</p>

Page 294	Page 296
<p>1 geographical dispensing patterns"? Did I read 2 that correctly?</p> <p>3 A. "Have very similar geographical 4 dispensing patterns," yes.</p> <p>5 Q. And then once again we see a map with 6 the legend that the more purple an area is, the 7 more 30-milligram Mallinckrodt extended units 8 have been sent into that area.</p> <p>9 Do you see that?</p> <p>10 A. Based on the map, yes.</p> <p>11 Q. And then do you see the State of 12 Tennessee is purple once again?</p> <p>13 A. Yes.</p> <p>14 Q. If you flip to the next page, there's 15 a -- it carries the title of "Per Capita Heat 16 Maps."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And then there are similar maps to the 20 one that we just went through. The first one 21 listed after that cover page is the one carrying 22 the title "The coasts have more per capita usage 23 than the midwest."</p> <p>24 Do you see that?</p>	<p>1 A. The All Strengths - Other 2 Manufacturers, yes.</p> <p>3 Q. And then also on the All Strengths - 4 Mallinckrodt map, the eastern portion of that 5 region is also green.</p> <p>6 Do you see that?</p> <p>7 A. No, because I see darker green spots 8 all throughout Tennessee.</p> <p>9 Q. I see.</p> <p>10 So you would agree with me that the 11 State of Tennessee is green in the All Strengths 12 - Mallinckrodt map?</p> <p>13 A. It's a light shade of green, yes.</p> <p>14 Q. And then once again if you'll flip 15 back to the 30-milligram page, a very similar 16 heat map showing the -- carrying the title "Per 17 capita usage of the Oxy 30 tablet is lowest in 18 the midwest." Did I read that correctly?</p> <p>19 A. Can you say that again, please?</p> <p>20 Q. Sure.</p> <p>21 The title of the 30-milligram slide is 22 that "Per capita usage of the Oxy 30 tablet is 23 lowest in the midwest."</p> <p>24 Did I read that correctly?</p>
<p style="text-align: center;">Page 295</p> <p>1 A. Yes.</p> <p>2 Q. And then again there's another map 3 showing per capita Oxy usage, and it appears 4 that the greener that you get in this map the 5 more per capita usage you see.</p> <p>6 Do you see that?</p> <p>7 A. Based on the map, yes.</p> <p>8 Q. And then on the "All Strengths - 9 Mallinckrodt," you'll see that Tennessee, and 10 particularly East Tennessee, is green.</p> <p>11 Do you see that?</p> <p>12 A. I don't know exactly where Tennessee 13 starts and ends, but --</p> <p>14 Q. Well, if you go over to the "All 15 Strengths - Other Manufacturers," the outline of 16 the State of Tennessee is a little bit more 17 prevalent there in the southeast portion of the 18 country.</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. And then if you -- the area, 22 especially the eastern portion of that area is 23 also lit up on the Mallinckrodt All Strengths 24 map, correct?</p>	<p style="text-align: center;">Page 297</p> <p>1 A. I went the wrong way.</p> <p>2 Q. I think it's the second-to-last, or 3 might be the very last page.</p> <p>4 A. Last page. Got it, yes.</p> <p>5 Q. And then once again on the 6 Mallinckrodt 30-milligram page, we see that 7 Tennessee is green, suggesting once again larger 8 per capita usage.</p> <p>9 Do you see that?</p> <p>10 A. I can't tell where Tennessee starts 11 and ends, but I see that there's green on the 12 map.</p> <p>13 Q. Sure.</p> <p>14 And then also over here on the 15 30-Milligram - Other Manufacturers, you also see 16 in the area of the State of Tennessee green, 17 suggesting greater per capita Oxy 30 usage in 18 the State of Tennessee, right?</p> <p>19 A. Based on these maps, yes.</p> <p>20 Q. And once again, not to belabor the 21 point, but apparently the source of the per 22 capita map is also this IMS, LRx, Xponent from 23 July 2012 to June 2013.</p> <p>24 Do you see that?</p>

Page 298	Page 300
<p>1 A. I see it. I don't know what it is.</p> <p>2 Q. Sure.</p> <p>3 Do you recall using these heat maps at</p> <p>4 all in the suspicious order monitoring program?</p> <p>5 A. I do not, no.</p> <p>6 Q. But you don't have a specific</p> <p>7 recollection as to whether or not the suspicious</p> <p>8 order monitoring program was generating these</p> <p>9 heat maps as part of its suspicious order</p> <p>10 monitoring program?</p> <p>11 A. Correct. Jen Buist was the analyst at</p> <p>12 the time responsible.</p> <p>13 Q. And do you know who Jen reported to?</p> <p>14 A. She started out reporting to Gail</p> <p>15 Tetzlaff, director of government reporting.</p> <p>16 Q. Okay. And then at some point did that</p> <p>17 change?</p> <p>18 A. Yes. Then she reported to Don Lohman</p> <p>19 in legal.</p> <p>20 (Whereupon, Mallinckrodt-Spaulding-44</p> <p>21 was marked for identification.)</p> <p>22 BY MR. GESTEL:</p> <p>23 Q. Same rules apply, by the way, if you</p> <p>24 need a break by all means, just say so and we</p>	<p>1 A. Sent to Ken Yamashita, the site</p> <p>2 director.</p> <p>3 Q. And he was the site director for what</p> <p>4 site?</p> <p>5 A. Hobart.</p> <p>6 Q. For Hobart?</p> <p>7 A. Yes.</p> <p>8 Q. And then if you flip over, this e-mail</p> <p>9 attaches this Word document carrying the title</p> <p>10 "Notes from Hobart Meeting with DEA Albany/NYC</p> <p>11 on SOM and Quota, 6/26/12."</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Do you recall this meeting with the</p> <p>15 DEA in June of 2012?</p> <p>16 A. To be honest, no, I don't.</p> <p>17 Q. And that's all right. But you see</p> <p>18 that you -- in the Mallinckrodt attendees you're</p> <p>19 listed there at the bottom, Eileen Spaulding?</p> <p>20 A. Yes.</p> <p>21 Q. Any reason to doubt that you were</p> <p>22 there?</p> <p>23 A. No, no. I'm sure I was there. I just</p> <p>24 don't remember it.</p>
Page 299	Page 301
<p>1 can take a break.</p> <p>2 A. Thank you.</p> <p>3 Q. I can assure you I will be much</p> <p>4 shorter in my examination than Mr. Gotto was</p> <p>5 this morning, but...</p> <p>6 I'll hand you a document that we'll</p> <p>7 mark as Exhibit 44. I do this once a deposition</p> <p>8 where I accidentally mark my copy, so just give</p> <p>9 me one second and let me flip this over. I</p> <p>10 should learn my lesson and that should be the</p> <p>11 last one that I mismark.</p> <p>12 This is an e-mail sent on June 29,</p> <p>13 2012 from you to Karen Harper carrying the</p> <p>14 subject line "DEA Albany/New York City Meeting</p> <p>15 notes on SOM/Quota."</p> <p>16 Did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. And you ask Karen Harper to "review</p> <p>19 and make edits/comments as you feel appropriate.</p> <p>20 Please advise when I may publish to Ken."</p> <p>21 Did I read that correctly?</p> <p>22 A. Yes.</p> <p>23 Q. Do you recall what you mean by this</p> <p>24 "publish to Ken" comment?</p>	<p>1 Q. And then apparently there was some</p> <p>2 question/answer between Mallinckrodt</p> <p>3 representatives and the DEA, and I want to</p> <p>4 direct your attention to the bottom of that</p> <p>5 first page of the Word document. There's a</p> <p>6 question there about "How long does it take to</p> <p>7 process lines?" Do you see that question?</p> <p>8 A. Yes.</p> <p>9 Q. And then the answer apparently given</p> <p>10 was "Reports are run daily at 9:00 a.m. and 3:00</p> <p>11 Central. The average time is 10 to 15 minutes</p> <p>12 to review and process each line that has gone on</p> <p>13 hold."</p> <p>14 Did I read that correctly?</p> <p>15 A. Yes.</p> <p>16 Q. Is that suggesting that processing</p> <p>17 lines, these are the orders that have been</p> <p>18 flagged by the suspicious order monitoring</p> <p>19 algorithm as needing further investigation?</p> <p>20 A. Yes.</p> <p>21 Q. And then the average time to process</p> <p>22 those were 10 to 15 minutes to review?</p> <p>23 A. Each line.</p> <p>24 Q. For each line?</p>

Page 302	Page 304
<p>1 A. For each order, yes.</p> <p>2 Q. Okay. Flip to the next page. Top of</p> <p>3 the page, the question "When you say 195 lines</p> <p>4 filed, what does it mean?" And then the answer</p> <p>5 is "It means that the line has hit the algorithm</p> <p>6 and requires review and/or investigation."</p> <p>7 Did I read that correctly?</p> <p>8 A. Yes.</p> <p>9 Q. Does that suggest that there's 195</p> <p>10 lines that are hitting the algorithm?</p> <p>11 A. It could.</p> <p>12 Q. And is that, do you know, or do you</p> <p>13 recall, is that 195 lines a month, a week, a</p> <p>14 day?</p> <p>15 A. I don't know the time period that Don</p> <p>16 was speaking to.</p> <p>17 Q. And you don't recall any specifically</p> <p>18 from this meeting?</p> <p>19 A. No. I mean, as I testified earlier, I</p> <p>20 remember reviewing our SOM program, but I don't</p> <p>21 remember specifics of the meeting.</p> <p>22 Q. Sure.</p> <p>23 And then the next question there is</p> <p>24 "How many orders have been deemed suspicious?"</p>	<p>1 Q. You can set that aside.</p> <p>2 (Whereupon, Mallinckrodt-Spaulding-45</p> <p>3 was marked for identification.)</p> <p>4 BY MR. GESTEL:</p> <p>5 Q. I'm going to hand you what's been</p> <p>6 marked as Exhibit 45. Sorry, I'm somehow down a</p> <p>7 copy.</p> <p>8 Do you see that this is a document</p> <p>9 Bates stamped MNK-T1_0006967775, and it's</p> <p>10 carrying the title "CSC Steering Committee</p> <p>11 Meeting Notes," December 12, 2012.</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. And you are on the suspicious order</p> <p>15 monitoring steering committee at that time,</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. And you see that there's a reference</p> <p>19 to introducing John?</p> <p>20 A. Yes.</p> <p>21 Q. Do you recall who that was?</p> <p>22 A. John Gillies.</p> <p>23 Q. And was he just coming on board at</p> <p>24 this time?</p>
<p style="text-align: center;">Page 303</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And then the answer is "None, it was</p> <p>4 explained that this updated SOM program went</p> <p>5 into place on 3/1/2012 and no orders have been</p> <p>6 determined to be suspicious since that date."</p> <p>7 Did I read that correctly?</p> <p>8 A. Correct.</p> <p>9 Q. Is that consistent with your</p> <p>10 recollection that there was no suspicious order</p> <p>11 reported on the updated SOM program since it</p> <p>12 went into place on March 1st of 2012?</p> <p>13 A. Between March 1st of 2012 and the date</p> <p>14 of this meeting on June 26th of 2012, correct.</p> <p>15 Q. And then does that -- taking that with</p> <p>16 the previous question, does that suggest to you</p> <p>17 that the 195 lines that were flagged were in</p> <p>18 that period between June 1st -- I'm sorry,</p> <p>19 March 1st, 2012 and the date of this meeting of</p> <p>20 June 26, 2012?</p> <p>21 MR. O'CONNOR: Object to form.</p> <p>22 A. I don't know. I wouldn't want to</p> <p>23 guess that that is.</p> <p>24 BY MR. GESTEL:</p>	<p style="text-align: center;">Page 305</p> <p>1 A. Yes.</p> <p>2 Q. Flip to the second page. There's some</p> <p>3 bullet items there, and it says, third one down,</p> <p>4 it says "We also dropped out," and I think</p> <p>5 that's a typo, it should be "our multiplier from</p> <p>6 █ to █."</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. So does that suggest to you that in</p> <p>10 December of 2012 that the suspicious order</p> <p>11 monitoring algorithm threshold was lowered from</p> <p>12 █ to █?</p> <p>13 A. Yes.</p> <p>14 Q. And then I believe that you testified</p> <p>15 earlier that eventually that was also further</p> <p>16 reduced down to █?</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. I don't remember stating that. I</p> <p>19 don't know that it's █. I know it went from 2</p> <p>20 to 3, we spoke about that earlier, but I don't</p> <p>21 remember that it went from █ down to █.</p> <p>22 BY MR. GESTEL:</p> <p>23 Q. So is the multiplier currently █?</p> <p>24 A. Yes.</p>

Page 306	Page 308
<p>1 Q. And do you believe that that's been 2 the case from December of 2012 to the present? 3 A. Based on my knowledge, yes. 4 Q. And then it has a description there, 5 "we multiply the 18 month average of orders on a 6 per customer, per SKU basis and multiply that 7 amount by [REDACTED] to get the level at which orders 8 will trip the volume flag that month. We do the 9 same for number of orders." 10 Did I read that correctly? 11 A. Yes. 12 Q. And is that a description of how the 13 algorithm functionally works? 14 A. One component of it. 15 Q. And so is it safe to say that once you 16 move the [REDACTED] multiplier, if an order was within 17 [REDACTED] times the 18-month moving average that that 18 order would not be flagged and would be 19 processed and shipped? 20 MR. O'CONNOR: Objection to form. 21 A. If it did not? Can you repeat that? 22 BY MR. GESTEL: 23 Q. Sure. 24 Is it safe to say that once you move</p>	<p>1 A. Yes. 2 Q. What is tier 1 and tier 2? 3 A. Tier 1 is the top three major 4 distributors for Oxy 15-milligram and Oxy 5 30-milligram. So if there -- it's a 6 multi-layered system. So tier 1 looks at Oxy 15 7 and Oxy 30s for the big three, and if the order 8 hits the threshold amount, then it will go on a 9 tier 1 hold. Tier 2 is based on all orders 10 being reviewed by an 18-month history. 11 Q. Okay. And am I understanding your 12 testimony correctly that only the big three 13 distributors would be in the tier 1? 14 A. Yes. 15 Q. And just for the record, who are the 16 big three? 17 A. McKesson, AmerisourceBergen, and 18 Cardinal. 19 Q. And then tier 2, am I understanding 20 your testimony correctly that that's essentially 21 everybody else? 22 A. That's everybody including the 23 distributors, but it's based on an 18-month -- 24 including the big three distributors for all</p>
Page 307	Page 309
<p>1 the [REDACTED] multiplier, if an order was within [REDACTED] 2 [REDACTED] the 18-month moving average 3 that order would not be flagged and would be 4 processed and shipped? 5 A. If it was less than [REDACTED], yes, that's 6 correct. 7 Q. And that would be the same for the 8 number of orders, right? 9 A. For this frequency, order frequency, 10 yes. 11 Q. And then -- and is that how the 12 algorithm continues to operate today? 13 A. Yes. 14 Q. For both volume of order and for the 15 number of orders? 16 A. Yes. 17 Q. And then if you flip -- continuing on 18 that page, it ends with this reference to "Jen 19 Buist Statistics." 20 Do you see that? 21 A. Yes. 22 Q. And then there's a reference to a tier 23 1 and a tier 2. 24 Do you see that?</p>	<p>1 products, but it's based on the 18-month 2 history. So that's where it's referring to the 3 multiplier above. 4 Q. Got it. 5 And then do you see that there's two 6 columns there of "Order Lines Processed" and 7 "Order Lines Failed"? Do you see that? 8 A. Yes. 9 Q. And in tier 1, just take March of 10 2012, there's 124 order lines processed and 56 11 order lines failed. 12 Do you see that? 13 A. Mm-hmm. 14 Q. So does that mean that in March of 15 2012, for tier 1 orders there were 124 of them? 16 A. There were 124 orders processed. 56 17 went on hold. 18 Q. And that means that it flagged the 19 algorithm? 20 A. Yes. 21 Q. Do you recall what was going on in 22 March of 2012 to suggest that high level of 23 flagging by the algorithm? 24 A. I don't. I know it's when the program</p>

Page 310	Page 312
<p>1 started, so I don't know if there was historical 2 data that needed to be loaded. 3 Q. Sure. 4 A. Or I don't remember specifically. 5 Q. And then you see for the rest of the 6 tier 1, that March of 2012 is an anomaly? Would 7 you agree with me with that? 8 A. Yes. 9 Q. So -- and then there's less orders 10 processed going down the line, and then 11 correspondingly less order fails, correct? 12 A. Correct. 13 Q. And again, that's the number of those 14 orders that are being flagged by the algorithm, 15 right? 16 A. Correct, for tier 1. 17 Q. So if you just look at the averages 18 here, you take an average, and it does the math 19 for you there, 78 average orders during that 20 time period, on average 7 monthly fails. 21 Do you see that? 22 A. It's 78 lines, not 78 orders. 23 Q. Sorry. Thank you. 24 78 lines, 7 line fails, right?</p>	<p>1 Q. And then 596 average order lines 2 hitting the algorithm, right? 3 A. Yes. 4 Q. And so that's approximately, just 5 doing the math, about 93 percent clearing the 6 algorithm and being processed and shipped, 7 right? 8 A. Yeah, I don't know the math, but -- 9 not my thing. 10 Q. And do you know, apart from sort of 11 that March, 2012 anomaly, do these statistics 12 hold from 2012 to the present, do you know? 13 A. I don't, not without running reports 14 and looking at them. 15 Q. And I assume that, again, based on the 16 document here, that Jen Buist must have ran 17 these statistics? 18 A. She did when she was in that role. 19 Q. And it sounds like she's no longer in 20 that role? 21 A. Correct. 22 Q. Who is in that role? 23 A. Rachelle Rogers. 24 Q. Do you know if the SOM steering</p>
Page 311	Page 313
<p>1 A. Yes. 2 Q. And just simple math, that suggests 3 that 90 percent of the orders are making its way 4 through the algorithm and being processed and 5 shipped, right? 6 A. If they don't hit tier 2 metrics, yes. 7 Q. Sure. 8 And then down on tier 2, it has the 9 same two columns, Order Lines Processed, Order 10 Lines Failed, right? 11 A. Yes. 12 Q. I don't want to belabor the point, but 13 again, these are lines that go through the 14 algorithm in tier 2, correct? 15 A. Mm-hmm. Sorry, yes. 16 Q. And then order lines failed are those 17 that are flagged by the algorithm for additional 18 investigation? 19 A. Yes. 20 Q. And then again taking the averages 21 here, the sheet does the math for you, that's on 22 average per month 8,436 lines on average are 23 processed per month, correct? 24 A. Yes.</p>	<p>1 committee is continuing to receive these types 2 of reports showing how many tier 1 and tier 2 3 order lines are being processed and hitting the 4 algorithm? 5 A. Not recently. 6 Q. And then we saw in the previous 7 document that when that investigation gets 8 tripped, the investigation takes 10 to 9 15 minutes, right? 10 A. On average. 11 Q. And is that continuing the average 12 from 2012 to the present? 13 A. I'd have to run reports. It's -- 14 every line is thoroughly investigated. 15 Q. And who would you go to to run that 16 report about how long it's taking to process the 17 orders that are being hit by the algorithm? 18 A. I would run it. 19 Q. You would run the report? 20 A. Mm-hmm. 21 Q. How would you do it? 22 A. We have a system. Well, let me 23 clarify. 24 So how long it takes to review, to</p>

Page 314	Page 316
<p>1 review and release an order if appropriate?</p> <p>2 Q. Yes.</p> <p>3 A. So I don't know that we'd have a</p> <p>4 mechanism to know that. It's human involvement,</p> <p>5 and I have an analyst that that's what her</p> <p>6 full-time job is, and she spends a good part of</p> <p>7 her day reviewing and releasing, so I don't --</p> <p>8 we don't have a mechanism that tracks exactly</p> <p>9 how long it takes.</p> <p>10 Q. And who is that analyst?</p> <p>11 A. Rachelle Rogers currently.</p> <p>12 Q. And how long has she been in that</p> <p>13 role?</p> <p>14 A. Since December.</p> <p>15 Q. And did she take over from Jennifer</p> <p>16 Buist?</p> <p>17 A. No. She took over from Amanda Chase</p> <p>18 who was in that role for approximately a year</p> <p>19 and a half.</p> <p>20 Q. And did Amanda Chase take over the</p> <p>21 role from Jennifer Buist?</p> <p>22 A. No. Previous to Amanda Chase it was</p> <p>23 done out in corporate by Heather McKenzie, and</p> <p>24 Jen Buist was previous to Heather McKenzie.</p>	<p>1 A. I would contact the finance analyst</p> <p>2 that has access to the chargeback system.</p> <p>3 Q. And who is that?</p> <p>4 A. Currently is Debbie Digby.</p> <p>5 Q. And who was it prior to Ms. Digby?</p> <p>6 A. I'm not sure who Jennifer was</p> <p>7 getting -- Jen Buist was getting them from.</p> <p>8 Q. And then have you ever had occasion to</p> <p>9 ask for chargeback data?</p> <p>10 A. Yes.</p> <p>11 Q. Any time when that request for</p> <p>12 chargeback data was refused?</p> <p>13 A. No.</p> <p>14 Q. You testified earlier that when</p> <p>15 Mallinckrodt terminated chargebacks to a</p> <p>16 pharmacy you reported this to the DEA and</p> <p>17 Mallinckrodt would inform the DEA through a</p> <p>18 letter. Do you remember that testimony?</p> <p>19 A. Yes.</p> <p>20 Q. Did Mallinckrodt maintain a copy of</p> <p>21 the letter that it sent to the DEA?</p> <p>22 A. Yes.</p> <p>23 Q. And did you send that letter?</p> <p>24 A. I send them currently. Previous to me</p>
<p style="text-align: center;">Page 315</p> <p>1 Q. Just forgive me, just give me one</p> <p>2 second because I ask a lot of questions that</p> <p>3 were already covered, and it's a lot easier for</p> <p>4 me just to look at my notes than to ask you all</p> <p>5 those questions again.</p> <p>6 As part of your role on the suspicious</p> <p>7 order monitoring steering committee, have you</p> <p>8 had a chance to review some chargeback data?</p> <p>9 A. Yes.</p> <p>10 Q. And this may have been covered</p> <p>11 earlier, but do you recall when chargeback data</p> <p>12 started being used by the suspicious order</p> <p>13 monitoring program at Mallinckrodt?</p> <p>14 A. So we reviewed some e-mails earlier</p> <p>15 today that gave a ballpark, but I don't remember</p> <p>16 exactly when.</p> <p>17 Q. And have you ever had occasion for</p> <p>18 yourself to request chargeback data?</p> <p>19 A. For myself?</p> <p>20 Q. Well, let me back up.</p> <p>21 Do you maintain the chargeback data?</p> <p>22 A. No.</p> <p>23 Q. If you needed a chargeback report run,</p> <p>24 how would you go about effectuating that?</p>	<p style="text-align: center;">Page 317</p> <p>1 would have been Jen Buist or Heather McKenzie.</p> <p>2 Q. Okay. And when did you start sending</p> <p>3 them?</p> <p>4 A. When SOM program transferred to Hobart</p> <p>5 back in April of 2017.</p> <p>6 Q. Okay. Thank you.</p> <p>7 I'm going to hand you a document that</p> <p>8 we marked as Exhibit 46.</p> <p>9 (Whereupon, Mallinckrodt-Spaulding-46</p> <p>10 was marked for identification.)</p> <p>11 BY MR. GESTEL:</p> <p>12 Q. And I promise you that we're near the</p> <p>13 end.</p> <p>14 You've been handed a document that's</p> <p>15 been marked as Exhibit 46. At the top of it,</p> <p>16 the title of this document is the "HZQS -</p> <p>17 Controlled Substances Compliance</p> <p>18 Responsibilities Associated with</p> <p>19 Anti-Diversion."</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes.</p> <p>22 Q. And you see the revision date is</p> <p>23 March 11, 2015.</p> <p>24 Do you see that?</p>

Page 318	Page 320
<p>1 A. Yes.</p> <p>2 Q. Do you know if this is -- continues to</p> <p>3 be the current policy?</p> <p>4 A. I don't.</p> <p>5 Q. Do you maintain the policies?</p> <p>6 A. I do not.</p> <p>7 Q. But you know that based on the record</p> <p>8 here that this was at least the portion that was</p> <p>9 in effect on March 11, 2015?</p> <p>10 A. Based on this document, yes.</p> <p>11 Q. And then if there are subsequent</p> <p>12 revisions, does the revision date gets updated</p> <p>13 and it supersedes the date of the previous</p> <p>14 revision?</p> <p>15 A. Correct, the next revision would move</p> <p>16 the March -- 03/11/2015 to supersedes date, and</p> <p>17 then become the new date.</p> <p>18 Q. Got it.</p> <p>19 I've handed you a document that we'll</p> <p>20 mark as Exhibit 47.</p> <p>21 (Whereupon, Mallinckrodt-Spaulding-47</p> <p>22 was marked for identification.)</p> <p>23 BY MR. GESTEL:</p> <p>24 Q. And this document is another SOM</p>	<p>1 February 19, 2015, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And then a supersedes date of a</p> <p>4 previous policy of November 14, 2013, right?</p> <p>5 A. Yes.</p> <p>6 Q. And then once again, we can assume</p> <p>7 that this is the policy that went into effect on</p> <p>8 February 19, 2015?</p> <p>9 A. Yes.</p> <p>10 Q. And then do you know if this is the</p> <p>11 current policy in effect?</p> <p>12 A. I don't.</p> <p>13 Q. But if it was revised, there would be</p> <p>14 a new revision date with the supersede date</p> <p>15 replaced with this February 19, 2015 date?</p> <p>16 A. Correct, if it had been approved.</p> <p>17 Q. That was my last policy. I hand you</p> <p>18 Exhibit Number 49.</p> <p>19 (Whereupon, Mallinckrodt-Spaulding-49</p> <p>20 was marked for identification.)</p> <p>21 BY MR. GESTEL:</p> <p>22 Q. This is an e-mail from you dated</p> <p>23 September 18, 2015 to Carrie Johnson, correct?</p> <p>24 A. Yes.</p>
<p>1 written policy. This one is entitled</p> <p>2 "Identification, Investigation, and Reports of</p> <p>3 Controlled Substances Suspicious Orders."</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. I don't want to belabor this too much,</p> <p>7 but same thing with regard to the effective date</p> <p>8 and supersede date is the same as the document</p> <p>9 that preceded this?</p> <p>10 A. Yes.</p> <p>11 Q. Do you know if this is the current</p> <p>12 in-force version of this policy?</p> <p>13 A. I don't.</p> <p>14 (Whereupon, Mallinckrodt-Spaulding-48</p> <p>15 was marked for identification.)</p> <p>16 BY MR. GESTEL:</p> <p>17 Q. You're going to notice a trend here.</p> <p>18 Exhibit 48 (handing). Once again, another SOM</p> <p>19 policy, this one entitled "Controlled Substances</p> <p>20 Compliance Responsibilities Associated with</p> <p>21 Suspicious Order Monitoring."</p> <p>22 Did I read that correctly?</p> <p>23 A. Yes.</p> <p>24 Q. And then there's a revision date of</p>	<p>1 Q. And it has -- carries the title</p> <p>2 "UO" -- or subject "UOR Program Review," right?</p> <p>3 A. Yes.</p> <p>4 Q. What is the UOR program?</p> <p>5 A. Unusual order reports.</p> <p>6 Q. And then if you flip back, you see</p> <p>7 that there are various attachments to this</p> <p>8 e-mail, right?</p> <p>9 A. Yes.</p> <p>10 Q. Do you recall sending this e-mail?</p> <p>11 A. I don't, no.</p> <p>12 Q. Any reason to believe that you did not</p> <p>13 send the e-mail?</p> <p>14 A. No.</p> <p>15 Q. And then if you flip back to the last</p> <p>16 page, there is a document entitled "Excluded</p> <p>17 Items within the UOR scope of JDE."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes.</p> <p>20 Q. What does that mean?</p> <p>21 A. So there's certain products that we</p> <p>22 make on behalf of other manufacturers, such as</p> <p>23 this Methylin Chewable, Methylin Oral,</p> <p>24 Tussicaps, and we do not distribute to the</p>

Page 322	Page 324
<p>1 market. So we're a contract marketing 2 organization for another manufacturer. 3 Q. Okay. And then do you see there's a 4 chart that says, two columns, "Reason" and then 5 "Definition"?</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. And then there are three reasons 9 listed. Under the second one, there's 10 "Xartemis XR." Did I say that correctly?</p> <p>11 A. Yeah, Xartemis.</p> <p>12 Q. Xartemis.</p> <p>13 And it says "added to table on 14 March 12, 2014. XXR deemed by SOM Team not 15 likely to be diverted into other than legitimate 16 medical channels."</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes.</p> <p>19 Q. What does that mean?</p> <p>20 A. It's a branded product, and it's very 21 small volume, very expensive, so there's not a 22 lot of it moving.</p> <p>23 Q. And so what does it mean that "XXR 24 deemed by SOM Team not likely to be diverted"?</p>	<p>1 Q. Got it. Actually that was my next 2 question.</p> <p>3 So when you say removed from the list, 4 it means removed from this carveout list from 5 the suspicious order monitoring -- or I'm sorry, 6 the algorithm processing?</p> <p>7 A. Correct, because they were both new 8 products that were launched, so there was no 9 history in the market to be able to measure 10 volumes against for previous orders.</p> <p>11 Q. Got it.</p> <p>12 So -- but then beginning on 13 January 22, 2015, these two items were then 14 added to the algorithm?</p> <p>15 A. Correct, because now we had a history 16 to know what customers would be ordering of it 17 to look at.</p> <p>18 Q. Got it.</p> <p>19 And is that true through today, that 20 those are being ran through the algorithm?</p> <p>21 A. Both products are discontinued, but 22 yes.</p> <p>23 Q. Got you.</p> <p>24 You went through with Mr. Gotto</p>
<p style="text-align: center;">Page 323</p> <p>1 A. It's -- XXR is the abbreviation for 2 Xartemis XR.</p> <p>3 Q. Got it.</p> <p>4 Does this mean that orders for this 5 particular item are not being run through the 6 algorithm?</p> <p>7 A. Yes.</p> <p>8 Q. And then the same thing here on the 9 next reason, "Generic Exalgo"?</p> <p>10 A. Correct.</p> <p>11 Q. It says it's added to the table on 12 May 15, 2014.</p> <p>13 A. Added to the table, yes.</p> <p>14 Q. And then "Generic Exalgo deemed by SOM 15 Team not likely to be diverted into other than 16 legitimate medical channels."</p> <p>17 Did I read that correctly?</p> <p>18 A. Correct.</p> <p>19 Q. Does that mean that orders for the 20 generic Exalgo are also not being run through 21 the algorithm?</p> <p>22 A. For both products until they were 23 removed on January 22, 2015, and then they were 24 being run.</p>	<p style="text-align: center;">Page 325</p> <p>1 some -- the memorandum of understanding entered 2 between Mallinckrodt and the United States 3 Department of Justice.</p> <p>4 Do you recall that testimony?</p> <p>5 A. The memorandum of agreement, yes.</p> <p>6 Q. Yes.</p> <p>7 Were you disciplined at all as a 8 result of the allegations by the Department of 9 Justice that led to that MOA?</p> <p>10 A. No.</p> <p>11 Q. Are you aware of anyone at 12 Mallinckrodt that was disciplined as a result of 13 the allegations that gave rise to the July, 2017 14 MOA with the United States Department of 15 Justice?</p> <p>16 A. No.</p> <p>17 Q. This must be music to your ears, 18 Ms. Spaulding, but that's all I have.</p> <p>19 THE VIDEOGRAPHER: The time is 20 5:40 p.m., and we're off the record.</p> <p>21 (Whereupon, a recess was taken.)</p> <p>22 THE VIDEOGRAPHER: The time is 23 5:40 p.m., and we're on the record.</p> <p>24 EXAMINATION</p>

Page 326	Page 328
1 BY MR. O'CONNOR:	1 That's it.
2 Q. Ms. Spaulding, I promise to be quick.	2 Go off the record.
3 Can you please take a look at Exhibit	3 THE VIDEOGRAPHER: The time is
4 Number 41, the memorandum of agreement? I just	4 5:43 p.m. This deposition has concluded, and we
5 want to make sure we have a very clear record on	5 are off the record.
6 this.	6 (Whereupon, the deposition was
7 Earlier today Mr. Gotto questioned you	7 concluded.)
8 with regard to the Background section on Page 1	8
9 of this agreement.	9
10 Do you recall that testimony?	10
11 A. Yes.	11
12 Q. Again, just so we have a clear record,	12
13 after you had a chance to review the language of	13
14 that Background section with Mr. Gotto, do you	14
15 agree with any of the allegations the United	15
16 States was making against Mallinckrodt in these	16
17 paragraphs 1 through 7?	17
18 A. No.	18
19 Q. Okay. And specifically you don't	19
20 agree, or do you agree with the United States --	20
21 strike that.	21
22 Do you agree with the allegations the	22
23 United States is making in paragraph 3	23
24 specifically?	24
Page 327	Page 329
1 A. No.	1 COMMONWEALTH OF MASSACHUSETTS)
2 Q. And do you agree with the allegations	2 SUFFOLK, SS.)
3 the United States is making in paragraph 5?	3 I, MAUREEN O'CONNOR POLLARD, RMR, CLR,
4 A. No.	4 and Notary Public in and for the Commonwealth of
5 Q. Okay. If you could turn to Page 3,	5 Massachusetts, do certify that on the 5th day of
6 I'll direct your attention to subparagraph B, as	6 February, 2019, at 9:06 o'clock, the person
7 in boy, Mr. Gotto asked you a series of	7 above-named was duly sworn to testify to the
8 questions about paragraph B. Do you recall	8 truth of their knowledge, and examined, and such
9 that?	9 examination reduced to typewriting under my
10 A. Yes.	10 direction, and is a true record of the testimony
11 Q. And how would you characterize the	11 given by the witness. I further certify that I
12 issues that are addressed in paragraph B?	12 am neither attorney, related or employed by any
13 MR. GOTTO: Object to form.	13 of the parties to this action, and that I am not
14 A. They are all documentation --	14 a relative or employee of any attorney employed
15 BY MR. O'CONNOR:	15 by the parties hereto, or financially interested
16 Q. Okay.	16 in the action.
17 A. -- instances.	17 In witness whereof, I have hereunto
18 Q. Are you aware of any evidence to	18 set my hand this 7th day of February, 2019.
19 suggest that any of the issues described in	19
20 paragraph B led to any controlled substance	20
21 leaving the Hobart facility?	21 MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
22 MR. GOTTO: Object to form.	22 Realtime Systems Administrator
23 A. No.	23 CSR #149108
24 MR. O'CONNOR: Okay. All right.	24

